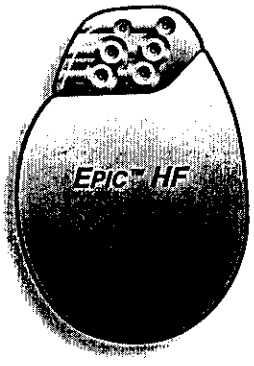
ST. JUDE MEDICAL



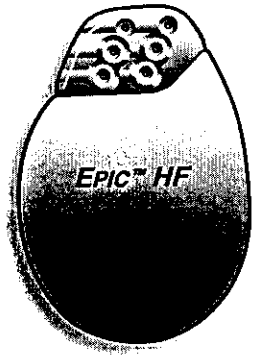
Epic™ HF
Model V-338

Cardiac Resynchronization Therapy Defibrillator

User's Manual

USER'S MANUAL

ST. JUDE MEDICAL



Epic™ HF
Model V-338

Cardiac Resynchronization Therapy Defibrillator

User's Manual

CAUTION
Federal (USA) law restricts this device to sale by or on order of a physician.

TABLE OF CONTENTS

PREFACE

This booklet describes the St. Jude Medical® Epic™ HF (Model V-338) cardiac resynchronization therapy defibrillator (also referred to as the "Epic HF pulse generator") along with implantation instructions. For information on programming the pulse generator, refer to the appropriate reference manual.

Typographic Conventions

This manual uses different formats to distinguish tasks, notes, cautions, and warnings.

1. Numbered paragraphs contain instructions.

   Paragraphs like this one provide explanations of the paragraph above it as well as additional information that might be useful at that point in the procedure.

Note

Notes provide useful or important information.

Caution

Precautions flag conditions that may damage the pulse generator or that may prevent its safe and effective use.

WARNING

Warnings call attention to potential safety hazards and situations that may cause personal injury.

Device Description

The St. Jude Medical® Epic™ HF cardiac resynchronization therapy defibrillator (CRT-D), Model V-338, monitors and regulates a patient's heart rate by providing ventricular tachyarrhythmia therapy and dual-chamber bradycardia pacing with ventricular resynchronization therapy.

The pulse generator, along with compatible, commercially available leads, constitutes the implantable portion of the CRT-D system. The lead systems are implanted using either transvenous or transthoracic techniques. The St. Jude Medical Model 3510 Programmer, the software Model 3307 version 3.2m[1] (or greater), and a telemetry wand constitute the external portion of the CRT-D system.

Indications and Usage

The St. Jude Medical (SJM) Epic HF System is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. The Epic HF System is also intended to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.

Contraindications

Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

1. For devices with serial numbers ≥13000, software Model 3307 version 4.5m (or greater).

WARNINGS AND PRECAUTIONS

Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

Lead system. Do not use another manufacturer's lead system without demonstrated compatibility as undersensing cardiac activity and failure to deliver necessary therapy may result.

Avoiding shock during handling. Program the device to Defib Off mode during surgical implant and explant or post-mortem procedures as well as when disconnecting leads as the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.

Additional pacemaker implanted. This device provides dual-chamber bradycardia pacing with ventricular resynchronization therapy. If another pacemaker is used, it should have a bipolar pacing reset mode and be programmed for bipolar pacing to minimize the possibility of the output pulses being detected by the device.

Sterilization, Storage and Handling

Resterilization. Do not resterilize and re-implant explanted pulse generators.

Use before date. Do not implant the device after the "use before" date because the battery may have reduced longevity.

If package is damaged. Do not use the device or accessories if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to St. Jude Medical.

Device storage. Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (See *Environmental and Medical Therapy Hazards* on page 3.) to avoid device damage. Store the device between 10° and 45° C (50° to 113° F) because temperatures outside this range may damage the device.

Temperature Equilibration. After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device

because cold temperature may affect initial device function.

Implantation and Device Programming

Do not position a magnet over the device as that suspends detection and treatment (unless the device has been programmed to ignore the magnet).

Replace the device when the battery voltage reaches 2.45 V.

Program device parameters as specified in the reference manual.

Follow-up Testing

Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Pulse Generator Explant and Disposal

Interrogate the device and program the pulse generator to Defib Off and Pacer Off before explanting, cleaning or shipping the device to prevent unwanted shocks.

Return all explanted pulse generators and leads to St. Jude Medical.

Never incinerate the device because of the potential for explosion. The device must be explanted before cremation.

Environmental and Medical Therapy Hazards

Patients should be directed to avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage, resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off

will usually allow the pulse generator to return to its normal mode of operation.

Hospital and Medical Environments

Electrosurgical cautery. Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the pulse generator and leads as possible.

External defibrillation. External defibrillation may damage the pulse generator or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporarily or permanently elevated pacing capture thresholds. Minimize current flowing through the pulse generator and lead system by following these precautions when using external defibrillation on a patient with a pulse generator:

- Position defibrillation paddles as far from the pulse generator as possible (minimum of 5 inches [13 cm])
- Use the lowest clinically appropriate energy output
- Confirm pulse generator function following any external defibrillation.

High radiation sources. Do not direct high radiation sources such as cobalt 60 or gamma radiation at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Lithotripsy. Lithotripsy may permanently damage the pulse generator. Avoid it unless the therapy site is not near the pulse generator and leads.

Diathermy. Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the pulse generator.

Magnetic resonance imaging (MRI). MRI may cause device malfunction or damage. If MRI must be used, patients should be closely monitored and programmed parameters should be verified upon cessation of MRI.

Ultrasound therapy. Diagnostic and therapeutic ultrasound treatment is not known to affect the function of the pulse generator.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far from the device/lead system as possible. Monitor cardiac activity during TENS use.

Radiofrequency ablation. Radiofrequency (RF) ablation in a patient with a pulse generator may cause device malfunction or damage.

Minimize RF ablation risks by:

- Programming the device to Defib Off and Pacer Off
- Avoiding direct contact between the ablation catheter and the implanted lead or pulse generator
- Positioning the groundplate so that the current pathway does not pass near the pulse generator system, i.e., place the groundplate under the patient's buttocks or legs
- Having external defibrillation equipment available.

Home and Occupational Environments

High-voltage power transmission lines. High-voltage power transmission lines may generate enough EMI to interfere with pulse generator operation if approached too closely.

Communication equipment. Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely.

Home appliances. Home appliances in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

Industrial equipment. A variety of industrial equipment produce EMI of sufficient field strength and modulation characteristics to interfere with proper operation of the pulse generator. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

Electronic Article Surveillance (EAS)

Advise patients that the Electronic Article Surveillance/Anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with the device. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

Metal Detectors

Advise patients that metal detector security systems such as those found in airports and government buildings emit signals that may interact with the device. It is very unlikely that these systems will interact with their device significantly. To minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering. Even so, the CRT-D system contains metal that may set off the airport security system alarm. If the alarm does sound, the patient should present security personnel with their patient identification card. If security personnel perform a search with a handheld wand, the patient should ask that they perform the search quickly, stressing that they should avoid holding the wand over the device for a prolonged period.

Cellular Phones

The pulse generator has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. Based on the results of this testing, the pulse generator should not be affected by the normal operation of cellular phones.

Adverse Events

The *Reported Adverse Events* on page 7 summarize the adverse events in the Resynchronization for HemodYnamic Treatment for Heart Failure Management (RHYTHM ICD) trial. The RHYTHM ICD study was a pro-

spective, multicenter, randomized, double-blind, controlled clinical investigation designed to assess the safety and efficacy of the Epic HF CRT-D system in patients who were indicated for standard implantable cardioverter defibrillation therapy with New York Heart Association Class III/IV heart failure and a prolonged QRS duration.

Per the investigational plan, an *adverse event* was defined as any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a Clinical Study participant caused by or associated with a study device or intervention. Adverse events were classified as complications or observations based on the following definitions:

- *Complications* are defined as adverse events that require invasive intervention (e.g. lead dislodgment requiring repositioning).
- *Observations* are defined as adverse events that can be managed without invasive intervention (e.g., oversensing or loss of pacing capture, which is then remedied by reprogramming of the pulse generator).
- *Other Reported Event* is defined as any other clinical event that was reported by the investigator, which is not an Adverse Event as defined above.

Reported Adverse Events

Table 1 lists the observations and complications reported from the RHYTHM ICD clinical trial (see *Summary Of Clinical Study* on page 17). A total of 97 adverse events have been reported in 70 patients, of which 29 are complications and 68 are observations.

Event Description	# of Patients with AEs* (n= 205)	% of Patients with AEs	# AEs	AE/pt-years (n=186.07 yrs)
Complications (total)	**21**	**10.2%**	**29**	**0.156**
Coronary Sinus Perforation/Dissection	2	1.0%	2	0.011
Diaphragmatic/Phrenic Nerve Stimulation	3	1.5%	3	0.016
Lead Dislodgment or Migration	8	3.9%	9	0.048
Bleeding/Hematoma†	6	2.9%	6	0.032
Blood Clot/Thrombosis	1	0.5%	1	0.005
High Defibrillation/Cardioversion Requirements	2	1.0%	2	0.011
Infection	1	0.5%	1	0.005
Noise on EGM Post Shock (Non-SJM RV lead)	1	0.5%	1	0.005
Pneumothorax	2	1.0%	2	0.011
Retained Foreign Body (surgical sponge)	1	0.5%	1	0.005
Elevated Pacing Threshold – LV Lead	1	0.5%	1	0.005

Table 1. Rhythm ICD Adverse Events

Event Description	# of Patients with AEs* (n= 205)	% of Patients with AEs	# AEs	AE/pt-years (n=186.07 yrs)
Observations (total)	**57**	**27.8%**	**68**	**0.365**
Asystolic Episode during LV Lead Placement	1	0.5%	1	0.005
Bleeding/Hematoma†	10	4.9%	10	0.054
Blood Clot/ Thrombosis	2	1.0%	2	0.011
Coronary Sinus Perforation/Dissection	6	2.9%	6	0.032
Diaphragmatic/Phrenic Nerve Stimulation – LV Lead	10	4.9%	10	0.054
Diaphragmatic/Phrenic Nerve Stimulation – RV Lead	2	1.0%	2	0.011
Elevated Pacing Thresholds – LV Lead	10	4.9%	10	0.054
Elevated Pacing Thresholds – RV Lead	2	1.0%	2	0.011
Heart Block at Implant	2	1.0%	2	0.011
High Defibrillation/Cardioversion Requirements	1	0.5%	1	0.005
Hypotension Requiring Ventilatory Support	1	0.5%	1	0.005
Inappropriate Therapy for SVT	10	4.9%	13	0.070
Infection	3	1.5%	3	0.016

Table 1. Rhythm ICD Adverse Events (continued)

Event Description	# of Patients with AEs* (n= 205)	% of Patients with AEs	# AEs	AE/pt-years (n=186.07 yrs)
Possible Pulmonary Embolism	1	0.5%	1	0.005
T-Wave Sensing	2	1.0%	3	0.016
Pocket Inflammation/Seroma	1	0.5%	1	0.005

Table 1. Rhythm ICD Adverse Events (continued)

* Some patients experienced more than one observation and/or complication and therefore the # of patients is less than the # of events.

† Fifteen (15) of the 16 patients with bleeding/hematoma related adverse events were on active anticoagulation therapy.

Event Description	# of Patients	# of Events	Comments
Atrial arrhythmias observed	7	8	Atrial arrhythmias noted on electrograms that did not result in therapy delivery.
Bacteremia	2	2	Chronically diagnosed Gram positive bacteremia, unrelated to implant procedure, treated with antibiotics.
Cardiopulmonary/respiratory arrest	1	1	Syncopal episode leading to brief respiratory arrest probably due to vagal response while retching with spontaneous resolution following re-hydration.
Cardioversion for arrhythmias below device detection	1	1	Cardioversion for ventricular tachycardia below the programmed detection rate on a patient treated with Amiodarone.
Chest pain/tightness	3	3	ER visit for chest pain associated with pleurisy (1 pt.); Chest pain associated with leaking thoracic aneurysm (1 pt.); Chest pain managed medically (1 pt.).
CNS related disorders	4	4	Seizure in 2 pt. with history of seizure disorder; changes in mental status (2 pts.): secondary to dementia in 1 pt. and wife withheld medication for 1 pt.
Crosstalk noted on electrogram	1	1	Resolved by reprogramming the ventricular blanking period.

Table 2. Other Reported Events

Event Description	# of Patients	# of Events	Comments
Fatigue/Shortness of breath	1	1	Shortness of breath/fatigue reported on a clinic visit possibly secondary to resolving pneumonia.
Hemoptysis	1	1	Blood noted in sputum; lung biopsy performed; no further events reported.
Inflammatory response/swelling/ elevated WBCs	3	3	General clinical symptoms evaluated and treated medically; no further sequelae reported.
Elective surgery	4	4	Left hydrocelectomy; cholecystectomy; hernia repair; percutaneous transluminal coronary angioplasty.
Inappropriate mode switches	8	10	Eight events were resolved with device re-programming.
Nausea/Vomiting/Diarrhea/ Abdominal pain or bloating	6	6	GI symptoms treated medically with no further sequelae.
Nose bleed	1	1	Resulted from elevated INR while on coumadin therapy; dose adjustment and no further sequelae.
Occasional Far-R sensing noted on electrogram	2	2	Did not result in mode switching or other inappropriate device behavior; devices re-programmed.

Table 2. Other Reported Events (continued)

Event Description	# of Patients	# of Events	Comments
Pacing sensation	3	4	Symptoms possibly associated with pacing felt in chest. 1 pt. required re-programming.
Pain not related to procedure	2	2	Pain not associated with the device implant procedure: 1 pt. was R/O ischemia and discharged and 1 pt. diagnosed with gangrene of leg.
Pericardial effusion/Pericarditis	2	2	Treated medically with NSAIDs; no further sequelae.
Post-operative pain at incision site	2	3	Post surgical incisional pain treated with analgesics; no further sequelae reported.
Renal insufficiency/Elevated BUN and creatinine	1	1	Acute renal failure secondary to bilateral renal artery stenosis; treated medically with no further sequelae reported.
Respiratory related events	8	11	Reports of pneumonia, cough, bronchitis, cold, or wheezing treated medically; no further sequelae.
Shocks delivered for SVT/Afib in ventricular fibrillation zone	4	5	Therapy delivery appropriate: device performed as programmed (SVT discrimination not available to be programmed in Fib zone).
Shocks for MTD/MTF during SVT episode	2	2	Therapy delivery appropriate: device and features performed as Programmed. 1 pt. was re-programmed and 1 pt. prescribed amiodarone therapy.

Table 2. Other Reported Events (continued)

Event Description	# of Patients	# of Events	Comments
Sinus bradycardia observed	4	4	2 pts. resolved by device reprogramming pacing rate; 2 pts. did not require re-programming.
Shortened AV delay caused by frequent PVC's	1	1	AV delay re-optimized by device reprogramming.
Stroke/TIA	2	2	TIA in setting of continuous AF at 3 mos. post-op in 1 pt.; Mid-cerebral artery CVA in 1 pt.
Syncope/Pre-syncope/Dizziness /Vasovagal/Hypotension	5	5	General clinical symptoms treated medically with IV fluids post-op (2 pts.) and rest (3 pts.); no further sequelae reported.
Replacement of RA lead during initial implant procedure	1	1	Replacement of RA lead due to helix extension mechanism failure during initial implant procedure.
VF episode requiring multiple external shocks prior to Epic HF system implant	1	1	Ventricular fibrillation episode that occurred in the EP lab during initial implant procedure and reported as possibly associated with hypokalemia.
Occasional noise/EMI noted on electrogram	2	3	Noise observed on atrial channel of stored electrogram was not reproduced in clinic; device re-programming was not required.
TOTAL	66*	95	

Table 2. Other Reported Events (continued)

* Some patients experienced more than one event, and therefore the number of patients is less than the number of events.

Seventeen (17) patients enrolled in the RHYTHM ICD clinical investigation were withdrawn from the study due to death. Three (3) of the deaths occurred in patients with an unsuccessful implant, 2 deaths occurred between the implant and the Baseline visit, 8 deaths occurred between Baseline and the 6-month visit and 4 deaths occurred after the 6-month visit. Five (5) of the seventeen deaths were considered to be *peri-operative mortalities* (occurred ≤ 30 days post-implant). There were no deaths classified as related to the pulse generator or lead system. The 3 deaths in patients with an unsuccessful Epic HF system implantation were not attributed to the attempted implantations.

A summary of the Events Committee death classifications are shown in Table 3.

Primary Cause	CRT OFF	CRT ON	N/A*	Total
Cardiac-Arrhythmic	0	0	0	0
Cardiac-Nonarrhythmic	1	1	4	6
Cardiac-Unknown	0	0	0	0
Non-Cardiac	2	7	1	10
Unknown	0	1	0	1
Total	**3**	**9**	**5**	**17**

Table 3. Events Committee Classification of Patient Deaths

* Death occurred in patients who did not have a successful Epic HF system implant (unrelated to the implant procedure) or death occurred before their Baseline visit and randomization

Potential Adverse Events

Possible adverse events (in alphabetical order) associated with the system, include, but are not limited to the following:

- Acceleration of arrhythmias (caused by device)

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Death
- Erosion
- Exacerbation of heart failure
- Excessive fibrotic tissue growth
- Extracardiac stimulation (phrenic nerve, diaphragm, chest wall)
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/ dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to a CRT-D system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost

- Imagined shocking (phantom shock).

Figure 1 depicts the RHYTHM ICD study design.

SUMMARY OF CLINICAL STUDY

The St. Jude Medical, Inc. Resynchronization for Hemo-dYnamic Treatment for Heart Failure Management (RHYTHM) ICD study was conducted under an IDE (investigational device exemption).

Study Design

The RHYTHM ICD study was a prospective, multicenter, randomized, double-blind, controlled clinical investigation designed to assess the safety and efficacy of the Epic HF CRT-D system in patients who were indicated for standard implantable cardioverter defibrillation therapy with New York Heart Association Classification of III or IV and a prolonged QRS duration. The products being evaluated were the Epic HF V-338[2] CRT-D and the Aescula and QuickSite LV leads.

2. The Epic HF Model V-338 devices included in the RHYTHM ICD study did not include the AutoIntrinsic Conduction Search or the Rate-Responsive PVARP programmable parameters, or device-based battery management. For information on these features, refer to the reference manual.

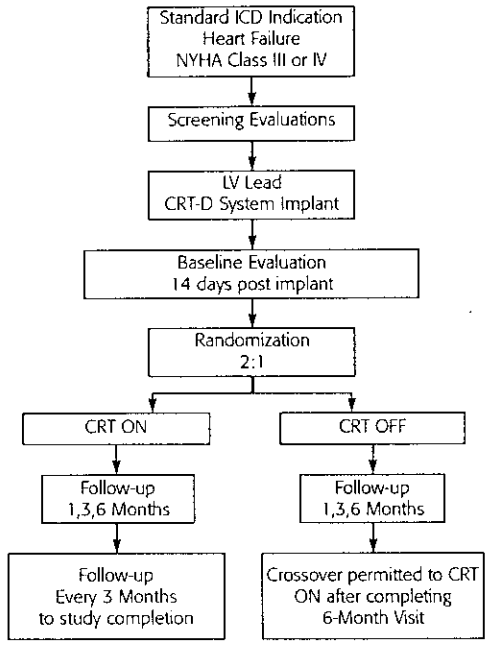


Figure 1. RHYTHM ICD Study Design

Study Objectives

The objective of this clinical study was to verify the safety and efficacy of the Epic HF CRT-D (Model V-338) system in a standard ICD indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration.

Primary Objectives

The following are the primary safety and efficacy objectives defined for this study.

- Safety of the Epic HF CRT-D system evaluated in terms of survival from LV lead and system related complications.
- Defibrillation system efficacy determined in terms of detection/redetection times and compared to those observed in the St. Jude Medical Photon DR clinical investigation.
- Resynchronization effectiveness evaluated in terms of exercise capacity, as measured by cardiopulmonary exercise testing.

Secondary Objectives

The secondary objectives are listed below.

- NYHA Classification
- Quality of Life Questionnaire
- 6-Minute Hall Walk Test
- Implant success rate for the Aescula Model 1055K LV pacing lead
- Aescula Model 1055K LV lead electrical performance

Patient Selection Criteria

Inclusion Criteria

Patients eligible for enrollment had:

- An approved indication for implantation of a standard ICD for treatment of a life-threatening ventricular tachyarrhythmia(s).
- Symptomatic, advanced heart failure (ischemic or non-ischemic) not due to reversible causes, diagnosed for at least 6 months.
- A New York Heart Association (NYHA) Classification of III or IV, despite receiving a minimum of 90 days of appropriate pharmacological therapy.
- Received optimal pharmacological therapy for CHF (including angiotensin converting enzyme inhibitor and beta blocker, as tolerated) which has been stable during the 30 days prior to enrollment.
- A left ventricular ejection fraction (LVEF) ≤ 35%.
- A ventricular conduction delay manifested as a QRS duration ≥ 150 ms.
- The ability to complete cardiopulmonary exercise stress testing and 6-minute hall walk test, with the only limiting factor(s) being fatigue and/or shortness of breath.
- The ability to independently comprehend and complete a quality of life questionnaire.
- The ability to provide informed consent for study participation and be willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria

Eligible patients did not/were not:

- Have a standard bradycardic indication for pacing.
- Have a history of chronic atrial fibrillation (continuous AF lasting > 1 Month) within 1 year prior to enrollment or have undergone cardioversion for AF in the past month.
- Have the ability to walk > 450 meters during the 6-minute walk test.
- Have a NYHA Classification of I or II.
- Have a contraindication for an emergency thoracotomy.
- Have a classification of Status 1 for cardiac transplantation or consideration for transplantation over the next 6 months.
- Have a recent myocardial infarction, unstable angina or cardiac revascularization (PTCA or CABG) within 1 month of enrollment.
- Have a recent CVA or TIA - within 3 months of enrollment.
- Have severe musculoskeletal disorder(s).
- Pregnant or a planning for pregnancy in the next 6 months.
- Currently participating in, or had participated in any clinical investigation within the last 30 days. (The only exception being that of a registry trial.)
- Have a life expectancy of less than 6 months.
- Less than 18 years of age.

Clinical Study Results

Patient Population

As of October 31, 2003, 205 patients were enrolled at 50 clinical sites in the RHYTHM ICD clinical investigation. The first Epic HF V-338 and Aescula 1055K left ventricular lead system was implanted on July 8, 2002. The first QuickSite 1056K lead was implanted on March 26, 2003.

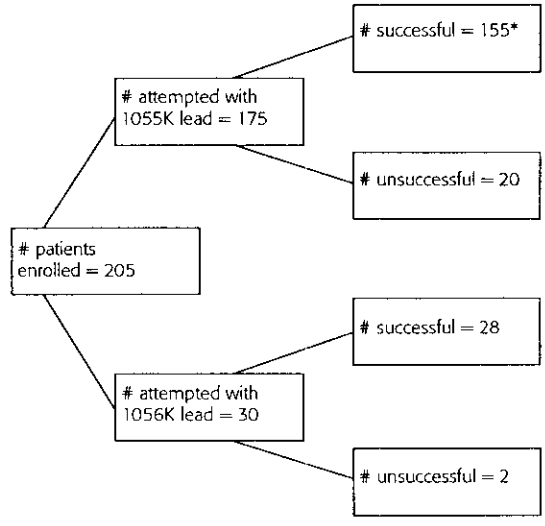
Of the 205 patients enrolled in the RHYTHM ICD study, one hundred and eighty-three (183) lead implant attempts were successful (180 successful on the first attempt and 3 successful on the second attempt). One additional patient had a successful left ventricular lead

implant, but had high defibrillation thresholds. This patient was withdrawn from the study and received a heart transplant, leaving a total of 182 successful system implants. Table 4 has a breakdown of the reasons for the 23 unsuccessful implants.

Reason	# Patients
LV Lead Related:	
Unable to Cannulate the CS	7
Unable to Obtain Distal Placement	6
Unable to Obtain Stable Lead Position	3
High Pacing Thresholds	3
CS Dissection	3
Other:	
High Defibrillation Threshold	1
TOTAL	**23**

Table 4. Unsuccessful Implants (N = 23)

Figure 2 displays the leads used and the number of successful system implants for each category of leads.



* Includes one patient with a successful lead implant, but an unsuccessful system implant due to high defibrillation thresholds

Figure 2. Number of Patients Attempted and Implanted with Model 1055K and 1056K Leads

As of March 17, 2004, the total time of follow-up from the time of successful implant was 2205 patient-months. The average time of follow-up was 12.1 ± 3.4 (range 0.3 to 20.3) patient-months.

Baseline Demographic Data

Patients who were successfully implanted with the Epic HF CRT-D system had a Baseline visit approximately two weeks after implant, during which the following tests/assessments were performed: Electrical measurements on RA, RV and LV leads, cardiopulmonary exercise (CPET) test, echocardiogram, NYHA class assessment, 6-minute walk test, and Minnesota Living with Heart Failure (MLWHF) questionnaire. Of the182 patients with successful implants, two patients expired and one patient withdrew from the study before the Baseline visit and therefore, 179 patients had a Baseline visit. One additional patient who had a Baseline follow-up visit refused randomization and all the Baseline evaluations except device interrogation and electrical measurements, but remained in the study. Therefore, a total of 178 patients completed the requirements of the Baseline visit.

Table 5 summarizes all the reported data on the 178 patients available for analysis at the Baseline visit, as well as broken down by randomization group.

Demographic variable	Overall Group (n = 178)*	CRT OFF (N = 59)	CRT ON (N = 119)	p-value (CRT ON vs. CRT OFF)
NYHA Class, n (%):				0.61
I	3 (1.7%)	2 (3.4%)	1 (0.8%)	
II	10 (5.6%)	4 (6.8%)	6 (5.0%)	
III	154 (86.5%)	50 (84.7%)	104 (87.4%)	
IV	11 (6.2%)	3 (5.1%)	8 (6.7%)	

Table 5. Summary of Baseline Variables and Comparisons Between CRT OFF and CRT ON groups

Demographic variable	Overall Group (n = 178)*	CRT OFF (N = 59)	CRT ON (N = 119)	p-value (CRT ON vs. CRT OFF)
LV Ejection Fraction (%) - ECHO:				
Mean ± SD	24.8 ± 7.7	23.3 ± 6.4	25.6 ± 8.3	0.07
Range	(9, 48)	(11, 43)	(9, 48)	
QRS Duration (ms):				
Mean ± SD	168 ± 15	167 ± 15	169 ± 16	0.40
Range	(120, 210)	(130, 200)	(120, 210)	
LVEDD (mm):				
Mean ± SD	66.2 ± 8.8	66.0 ± 9.4	66.2 ± 8.5	0.88
Range	(47.7, 85.9)	(50.1, 84.2)	(47.7, 85.9)	
LVESD (mm):				
Mean ± SD	57.0 ± 9.87	56.9 ± 10.5	57.1 ± 9.4	0.93
Range	(37.1, 78.2)	(37.9, 78.2)	(37.1, 76.2)	
Quality of Life Score:				
Mean ± SD	48 ± 24	46 ± 24	48 ± 24	0.53
Range	(0, 103)	(4, 100)	(0, 103)	
Six-Minute Walk (meters):				
Mean ± SD	280 ± 99	291 ± 89	275 ± 103	0.30
Range	(31, 561)	(31, 480)	(37, 561)	

Table 5. Summary of Baseline Variables and Comparisons Between CRT OFF and CRT ON groups (continued)

Demographic variable	Overall Group (n = 178)*	CRT OFF (N = 59)	CRT ON (N = 119)	p-value (CRT ON vs. CRT OFF)
CPET Test:				
Peak VO_2 (ml/kg/min):				
Mean ± SD	11.3 ± 3.3	12.3 ± 3.5	10.8 ± 3.0	0.006
Range	(4.3, 26.9)	(6.0, 23.1)	(4.3, 26.9)	
Exercise Time (minutes):				
Mean ± SD	8.3 ± 3.3	8.9 ± 3.6	8.0 ± 3.2	0.08
Range	(0.7, 19.8)	(2.3, 19.8)	(0.7, 16.5)	
Baseline Medications, n (%):				
ACE Inhibitors/Substitutes	129 (72.5%)	44 (74.6%)	85 (71.4%)	0.79
Beta Blockers	147 (82.6%)	52 (88.1%)	95 (79.8%)	0.24
Angiotensin Receptor Blockers	34 (19.1%)	10 (16.9%)	24 (20.2%)	0.76
Diuretics	157 (88.2%)	54 (91.5%)	103 (86.6%)	0.47
Positive Inotropics/Glycoside	112 (62.9%)	39 (66.1%)	73 (61.3%)	0.65
Nitrates	62 (34.8%)	23 (39.0%)	39 (32.8%)	0.51
Anti-Coagulants and Anti-Platelets	150 (84.3%)	48 (81.4%)	102 (85.7%)	0.59
Calcium Channel Blockers	20 (11.2%)	9 (15.3%)	11 (9.2%)	0.35
Anti-Arrhythmics	42 (23.6%)	13 (22.0%)	29 (24.4%)	0.87

Table 5. Summary of Baseline Variables and Comparisons Between CRT OFF and CRT ON groups (continued)

* Of the 182 patients that had successful system implants, two patients expired and one patient withdrew from the study before their Baseline visit; one additional patient refused randomization and all Baseline evaluations, except device interrogation and electrical measurements, and therefore, is not included.

Primary Safety Endpoint Results

LV Lead-Related Complications (at 6 Months)

Table 6 summarizes the LV Lead Related Complications at 6 months. One hundred and fifty-five (155) patients who had a successful 1055K LV lead implant were analyzed for this endpoint. A total of 11 patients experienced 13 1055K LV lead related complications.

The survival from 1055K lead related complications at 6-months was calculated as 92.8% with a 95% lower confidence bound of 89.4%, which is greater than the objective performance criteria of 75%.

Description of Complication	Number of Events	Number of Patients
Diaphragmatic Stimulation	3	3
Lead Dislodgment/Migration	9	8
Elevated Pacing Threshold	1	1
TOTAL	13	11*

Table 6. Aescula 1055K LV Lead Related Complications

* One patient experienced both a lead dislodgment/migration and diaphragmatic stimulation, and one patient experienced two lead dislodgments/migrations.

Epic HF System-Related Complications (at 6 Months)

Table 7 summarizes the System Related Complications at 6 months. One hundred and eighty-two (182) patients who had a successful Epic HF system implant with either the Aescula or QuickSite LV lead were analyzed for this endpoint. A total of 13 patients experienced 16 Epic HF system-related complications.

The survival from system-related complications at 6-months was calculated as 93.4% with a 95% lower confidence bound of 90.6%, which is greater than the objective performance criteria of 70%.

Description of Complication	Number of Events	Number of Patients
Diaphragmatic Stimulation	3	3
High Defibrillation/Cardioversion Requirements	2	2
Infection	1	1
Lead Dislodgment/Migration	9	8
Elevated Pacing Threshold	1	1
TOTAL	16	13*

Table 7. Epic HF System-Related Complications

* One patient experienced both a lead dislodgment/migration and diaphragmatic stimulation, one patient experienced two lead dislodgments/migrations, and one patient had high defibrillation threshold and lead dislodgment/migration.

Survival from All Complications (at 6 months)

In addition to the protocol-specified LV-lead related and system-related complication endpoints, survival from all complications at 6 months, including procedural complications and patients with unsuccessful implants, was analyzed following a review of the clinical results.

Two hundred and five (205) patients who were attempted with the Epic HF system were included in this analysis. Table 8 lists all complications experienced by each patient. A total of 21 patients experienced 29 complications.

The survival from all complications at 6-months was calculated as 90.1% with a 95% lower confidence bound of 86.5%.

Description of Complication	Number of Events	Number of Patients
Bleeding/Hematoma	6	6
Blood Clot/Thrombosis	1	1
CS Dissection	2	2
Diaphragmatic/Phrenic Nerve Stimulation	3	3

Table 8. All Complications

Description of Complication	Number of Events	Number of Patients
High Defibrillation/Cardioversion Requirements	2	2
Infection	1	1
Noise on EGM Post Shock (non-SJM RV lead)	1	1
Lead Dislodgment/Migration	9	8
Retained Foreign Body	1	1
Pneumothorax	2	2
Elevated Pacing Threshold	1	1
TOTAL	29	21*

Table 8. All Complications (continued)

* Five patients each experienced 2 complications and one patient experienced 4 complications.

Primary Effectiveness Endpoint Results

Defibrillation System Effectiveness: VF Detection/Redetection Times

The defibrillation system effectiveness of the Epic HF CRT-D system was evaluated by comparing the time to detect or redetect an episode of ventricular fibrillation to performance criteria established in the protocol based on historical data from the Photon DR study (P910023/S47). A total of 440 episodes in 172 patients were analyzed for detection times, and 90 episodes in 55 patients were analyzed for redetection times.

Table 9 displays a summary of the detection and redetection times for VF episodes. The mean detection and redetection times were within the objective performance criteria of 3.4 seconds and 1.9 seconds, respectively. The p-values for the detection and redetection time hypotheses were less than 0.0004. The 95% upper confidence bound was 3.11 seconds for the mean detection time and 1.61 seconds for the redetection time.

Summary	Detection Time	Redetection Time
n (episodes)	440	90
N (patients)	172	55
Mean ± SD	3.1 ± 0.66	1.6 ± 0.35
Range	(1.5, 6.8)	(0.8, 2.8)

Table 9. Summary of VF Detection and Redetection Times

Primary Cardiac Resynchronization Therapy Efficacy Endpoint

The resynchronization effectiveness of the Epic HF CRT-D system was evaluated by comparing the CRT ON group to the CRT OFF group for peak VO_2, an indicator of a patient's maximal exercise capacity. Patients completed a CPET at the baseline visit approximately two weeks after their CRT-D implant, and again at the 6-month visit. The sample size required to satisfy this endpoint was 126 patients.

In the intention-to-treat analysis, patients who crossed over from the CRT OFF group to the CRT ON group during the study were analyzed according to the original treatment group they belonged to.

Table 10 contains a summary of the improvement in peak VO_2 values in the two treatment groups for this analysis. The average improvement in the CRT ON group over the CRT OFF group was approximately 1.9 ml/kg/min. The p-value was 0.001.

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	12.8 ± 3.7	11.2 ± 3.0
6-months	11.4 ± 5.6	11.7 ± 3.2
Change	-1.41 ± 4.6	0.52 ± 2.5
Overall improvement in CRT ON vs. CRT OFF = 1.9 ml/kg/min		

Table 10. Improvement in Peak VO_2 Values (ml/kg/min) Intention-To-Treat Analysis (N = 126)

Analysis of Exercise Time

The improvement in exercise time between the Baseline and 6-month visits was analyzed. Patients who were not able to perform the CPET at 6-months due to documented heart failure were assigned exercise times of 0. Table 11 shows that the CRT ON group had an improvement in exercise time over the CRT OFF group of approximately 109 seconds. The p-value was 0.002.

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	558 ± 216	498 ± 192
6-months	510 ± 270	558 ± 210
Change	-50.4 ± 252	58.2 ± 132
Overall improvement in CRT ON vs. CRT OFF = 109 seconds		

Table 11. Change in Exercise Time (seconds) (N = 126)

Secondary Endpoint Results

Resynchronization Effectiveness

Secondary endpoints for resynchronization effectiveness were NYHA class, Quality of Life, and the 6-Minute Hall Walk Test. These endpoints were evaluated on the same patient group that was analyzed for the Peak VO_2 endpoint.

New York Heart Association Classification

Table 12 shows the average change in NYHA Class from Baseline to 6 months for each group. Overall the improvement in the CRT ON group was greater than the improvement in the CRT OFF group by approximately 0.2 functional classes. The p-value was 0.048.

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	2.86 ± 0.52	3.01 ± 0.33
6-months	2.58 ± 0.73	2.53 ± 0.69
Change	-0.28 ± 0.63	-0.48 ± 0.65
Overall change in CRT ON vs. CRT OFF = 0.2 functional classes		

Table 12. Average Improvement in NYHA Class (N = 126)

Quality of Life

Patient quality of life was assessed with the MLWHF questionnaire. A lower score indicates an improvement in quality of life.

Table 13 contains a summary of the improvement in quality of life in the two treatment groups. The average improvement in the CRT ON group over the CRT OFF group was approximately 11 points. The p-value was 0.009.

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	42.0 ± 23	48.3 ± 24
6-months	45.4 ± 31	40.4 ± 22
Change	3.4 ± 31	-7.8 ± 22
Overall improvement in CRT ON vs. CRT OFF = 11 points		

Table 13. Improvement in Quality of Life Score (N = 126)

6-Minute Hall Walk Test

Table 14 contains a summary of the improvement in 6-minute walk distance in the two treatment groups for this analysis. The average improvement in the CRT ON group over the CRT OFF group was approximately 28 meters. The p-value was 0.07.

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	298 ± 94	284 ± 105
6-months	283 ± 150	297 ± 122
Change	-15 ± 142	13 ± 74
Overall improvement in CRT ON vs. CRT OFF = 28 meters		

Table 14. Improvement in 6-minute Walk Distance (meters) (N = 126)

Additional Data

Echocardiographic Data

Echocardiographic analysis was performed at the Baseline and 6-month follow-up visits. The following parameters were evaluated from the echocardiographic analysis: LVEDD, LVESD, LVEF, MR, E/A Wave Point Ratio, and Sphericity Index. Cardiac dyssynchrony (including Pre-Ejection Delay Time and Intraventricular Mechanical Delay) was also evaluated at Baseline and 6-Months. Table 15 displays summaries of the improvement in these parameters between Baseline and 6-months.

Parameter	CRT OFF Mean ± SD (N = 40)	CRT ON Mean ± SD (N = 82)
LVEDD (mm)	-2.4 ± 6.5	-4.3 ± 5.4
LVESD (mm)	-3.0 ± 6.4	-4.6 ± 7.0
LVEDV (ml)	-37 ± 53	-43 ± 69
LVESV (ml)	-36 ± 47	-43 ± 58
LVEF (%)	2.9 ± 6.2	4.3 ± 9.9
MR (grade)	0.10 ± 0.50	-0.06 ± 0.74
E/A Wave Point Ratio	-0.02 ± 1.2	-0.08 ± 0.8
Sphericity Index	0.02 ± 0.1	-0.02 ± 0.1
Pre-Ejection time (ms)	7.3 ± 33	-1.5 ± 52
IVMD (ms)	-6.4 ± 48	-14.5 ± 52
Tei Index	-0.05 ± 0.5	-0.4 ± 0.8
Contraction Interval (ms)	-55 ± 103	-94 ± 124

Table 15. Improvement in Echocardiography Parameters

Biventricular Pacing at 6-months

The average percentage of biventricular pacing at the 6-month visit in the 83 patients who were in the CRT ON group among the 126 patients in the primary resynchronization cohort was 95% ± 6%, with a range of 70 to 100%.

Patient Discontinuation/Withdrawals

A total of 41 patients participating in the RHYTHM ICD study were withdrawn from the study. Twenty (20) patients (including the 19 patients with unsuccessful LV lead implants and the one patient with an unsuccessful system implant due to high defibrillation thresholds) were withdrawn approximately one month after unsuccessful system implants in accordance with the protocol. Seventeen (17) patients died and were also withdrawn from the study. Three of the 17 deaths occurred in patients who had previously unsuccessful implants. In addition to these 20 unsuccessful implants and 17 deaths, 4 additional patients were withdrawn from the study. Table 16 summarizes the reason for these 4 patient withdrawals.

Reason for Withdrawal	CRT Group	Days after Implant
System Explant	N/A*	1
Heart Transplant	ON	75
Patient Request	ON	28
Patient's Family Request	ON	293

Table 16. Patient Discontinuations/Withdrawals (Excludes Withdrawals for Deaths and after Unsuccessful Implants)

* Patient was withdrawn before the Baseline visit and randomization.

Conclusions Drawn From The Studies

In NYHA Class III and IV heart failure patients with LV dyssynchrony and a standard ICD indication, this study demonstrated that cardiac resynchronization is safe and improves functional status.

Patient Selection and Treatment

Pectoral or abdominal implant site. Evaluate the prospective patient's size and activity level to determine whether a pectoral or abdominal implant is suitable.

Exercise stress testing. If the patient's condition permits, use exercise stress testing to:

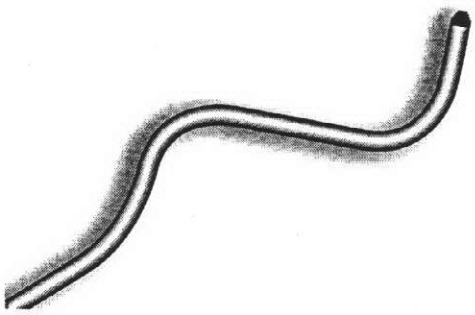
- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

Electrophysiologic (EP) testing. It is strongly recommended that candidates for CRT-D therapy have a complete cardiac evaluation, including EP testing. EP testing should identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or during EP testing.

ST. JUDE MEDICAL

USER'S MANUAL

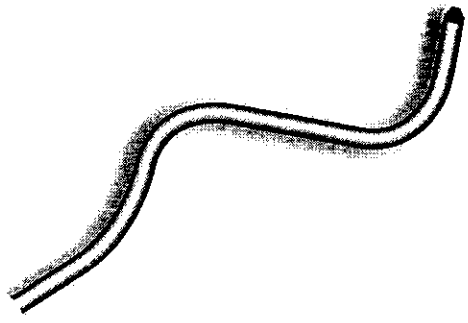


AESCULA™ LV
Model 1055K

Unipolar, Silicone, Titanium Nitride Left Heart Lead

User's Manual

ST. JUDE MEDICAL



AESCULA™ LV
Model 1055K

Unipolar, Silicone, Titanium Nitride Left Heart Lead

User's Manual

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

TABLE OF CONTENTS

DESCRIPTION

The Aescula™ LV Model 1055K lead is a silicone-insulated left heart lead with a Titanium Nitride (TiN) coated platinum-iridium electrode, designed for use with implantable pulse generators for long-term cardiac pacing. The distal portion of the tip is preshaped by the silicone insulation into an "s-curve" to provide passive fixation.

The lead length is 75 centimeters, and the minimum recommended lead introducer size is 7.0 French. The lead complies with IS-1 connector standard ISO 5841-3.

The Aescula LV Model 1055K lead is a unipolar lead, having one conductor that terminates at the tip electrode.

Features of the Aescula LV Model 1055K lead include:

- Passive Fixation — incorporating an s-shaped curve designed to stabilize the lead in the vein.
- Fast-Pass™ Coating — creates a lubricious surface.

INDICATIONS AND USAGE

The Aescula™ LV Model 1055K lead has application as part of a St. Jude Medical® biventricular system.

Contraindications

The Aescula™ lead is contraindicated in patients:

- Who are unable to undergo an emergent thoracotomy procedure, and
- With coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

WARNINGS AND PRECAUTIONS

Lead Selection

- Before opening the lead package, confirm that it is compatible with the pulse generator to be implanted.
- *Ventricular leads with polished platinum tip electrodes.* Pairing the Model 1055K ventricular lead with a polished platinum tip electrode lead may create a source impedance mismatch that could adversely affect sensing. Therefore, in the use of these leads, evaluate adequate sensing performance at the time of implant.

Storage and Handling

- For single use only.
- Do not sterilize the lead using an autoclave, gamma radiation, or ultrasonics; if sterilization is required, see page 14.
- Do not stretch, crush, kink or bend the lead. Leads may be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- Do not bring the lead into contact with sharp objects that could puncture or otherwise compromise the insulation.
- Handle the lead only with powderless, sterile surgical gloves.
- Avoid handling the lead with any surgical tools such as hemostats, clamps or forceps.
- Leads have an electrostatic attraction for particulate matter; do not expose them to lint, dust or other such materials.
- Avoid touching or handling the lead tip electrode itself.
- Do not immerse the lead body in mineral oil, silicone oil or any liquid other than sterile saline or injectable fluid.

- Do not immerse the tip electrode in any fluid prior to implantation.

Lead Implantation

- Lead implantation should be performed only when proper emergency facilities for cardioversion and/or defibrillation are available.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- During this procedure it is advisable to also have echocardiographic equipment available.
- If subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.
- Do not slide the suture sleeve over the connector pin sealing rings. This could result in damage to the lead.
- Failure to use the suture sleeve to secure the lead may result in lead dislodgment or in damage to the lead's insulation and/or conductor coil.

Adverse Events

Reported Adverse Events summarizes the adverse events in the Resynchronization for HemodYnamic Treatment for Heart Failure Management (RHYTHM ICD) trial for patients implanted with Epic HF V-338 devices and Aescula 1055K leads. The RHYTHM ICD study was a prospective, multicenter, randomized, double-blind, controlled clinical investigation designed to assess the safety and efficacy of the Epic HF CRT-D system in patients who were indicated for standard implantable cardioverter defibrillation therapy with New York Heart Association Class III/IV heart failure and a prolonged QRS duration. Per the investigational plan, an adverse event was defined as any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a Clinical Study participant caused by or associated with a study device or intervention. Adverse events were classified as complications or observations based on the following definitions:

- Complications are defined as adverse events that require invasive intervention (e.g. lead dislodgment requiring repositioning).
- Observations are defined as adverse events that can be managed without invasive intervention (e.g., oversensing or loss of pacing capture, which is then remedied by reprogramming of the pulse generator).
- Other Reported Event is defined as any other clinical event that was reported by the investigator, which is not an Adverse Event as defined above.

Reported Adverse Events

Table 1 lists the observations and complications reported from the RHYTHM ICD clinical trial for patients implanted with Epic HF V-338 devices and Aescula 1055K leads (see *RHYTHM ICD Clinical Study* on page 8). A total of 90 adverse events have been reported, of which 28 are complications and 62 are observations.

Event Description	# of Patients with AEs* (N=175)	% of Patients with AEs	# AEs	AE/pt-years (N= 163.32 yrs)
Complications (total)	**20**	**11.4%**	**28**	**0.171**
Bleeding/Hematoma	6	3.4%	6	0.037
Blood Clot/Thrombosis	1	0.6%	1	0.006
Coronary Sinus Perforation/Dissection	2	1.1%	2	0.012
Diaphragmatic/Phrenic Nerve Stimulation	3	1.7%	3	0.018
Elevated Pacing Threshold – LV Lead	1	0.6%	1	0.006
High Defibrillation/Cardioversion Requirements	2	1.1%	2	0.012
Lead Dislodgment or Migration	8	4.6%	9	0.055
Noise on EGM Post Shock (Non-SJM RV lead)	1	0.6%	1	0.006
Pneumothorax	2	1.1%	2	0.012
Retained Foreign Body (surgical sponge)	1	0.6%	1	0.006
Observations (total)	**52**	**29.7%**	**62**	**0.380**
Asystolic Episode during LV Lead Placement	1	0.6%	1	0.006
Bleeding/Hematoma	9	5.1%	9	0.055
Blood Clot/Thrombosis	2	1.1%	2	0.012
Coronary Sinus Perforation/Dissection	6	3.4%	6	0.037
Diaphragmatic/Phrenic Nerve Stimulation – LV Lead	9	5.1%	9	0.055
Diaphragmatic/Phrenic Nerve Stimulation – RV Lead	1	0.6%	1	0.006
Elevated Pacing Thresholds – LV Lead	9	5.1%	9	0.055
Elevated Pacing Thresholds – RV Lead	1	0.6%	1	0.006
Heart Block at Implant	2	1.1%	2	0.012
High Defibrillation/Cardioversion Requirements	1	0.6%	1	0.006
Hypotension Requiring Ventilatory Support	1	0.6%	1	0.006
Inappropriate Therapy for SVT	9	5.1%	12	0.073
Infection	3	1.7%	3	0.018
Pocket Inflammation/Seroma	1	0.6%	1	0.006
Possible Pulmonary Embolism	1	0.6%	1	0.006
T-Wave Sensing	2	1.1%	3	0.018

Table 1. Rhythm ICD Adverse Events

* Some patients experienced more than one observation and/or complication and therefore the # of patients is less than the # of events.

Table 2 lists the other reported events from the RHYTHM ICD clinical trial for patients implanted with Epic HF V-338 devices and Aescula 1055K leads.

Event Description	# of Patients	# of Events	Comments
Atrial arrhythmias observed	7	8	Atrial arrhythmias noted on electrograms that did not result in therapy delivery.
Bacteremia	2	2	Chronically diagnosed Gram positive bacteremia, unrelated to implant procedure, treated with antibiotics.
Cardiopulmonary/respiratory arrest	1	1	Syncopal episode leading to brief respiratory arrest probably due to vagal response while retching with spontaneous resolution following re-hydration.
Cardioversion for arrhythmias below device detection	1	1	Cardioversion for ventricular tachycardia below the programmed detection rate on a patient treated with Amiodarone.
Chest pain/tightness	3	3	ER visit for chest pain associated with pleurisy (1 pt.); Chest pain associated with leaking thoracic aneurysm (1 pt.); Chest pain managed medically (1 pt.).
CNS related disorders	4	4	Seizure in 2 pts. with history of seizure disorder; changes in mental status (2 pts.): secondary to dementia in 1 pt. and wife withheld medication for 1 pt.
Crosstalk noted on electrogram	1	1	Resolved by reprogramming the ventricular blanking period.
Elective surgery	3	3	Left hydrocelectomy; hernia repair; percutaneous transluminal coronary angioplasty.
Fatigue/Shortness of breath	1	1	Shortness of breath/fatigue reported on a clinic visit possibly secondary to resolving pneumonia.
Hemoptysis	1	1	Blood noted in sputum; lung biopsy performed; no further events reported.
Inappropriate mode switches	8	10	Eight events were resolved with device re-programming.
Inflammatory response/swelling/ elevated WBCs	3	3	General clinical symptoms evaluated and treated medically; no further sequelae reported.

Table 2. Other Reported Events

Event Description	# of Patients	# of Events	Comments
Nausea/Vomiting/Diarrhea/ Abdominal pain or bloating	6	6	GI symptoms treated medically with no further sequelae.
Nose bleed	1	1	Resulted from elevated INR while on coumadin therapy; dose adjustment and no further sequelae.
Occasional Far-R sensing noted on electrogram	2	2	Did not result in mode switching or other inappropriate device behavior; devices re-programmed.
Occasional noise/EMI noted on electrogram	2	3	Noise observed on atrial channel of stored electrogram was not reproduced in clinic; device re-programming was not required.
Pacing sensation	3	4	Symptoms possibly associated with pacing felt in chest. 1 pt. required re-programming.
Pain not related to procedure	2	2	Pain not associated with the device implant procedure: 1 pt. was R/O ischemia and discharged and 1 pt. diagnosed with gangrene of leg.
Pericardial effusion/Pericarditis	1	1	Treated medically with NSAIDs; no further sequelae.
Post-operative pain at incision site	2	3	Post surgical incisional pain treated with analgesics; no further sequelae reported.
Renal insufficiency/Elevated BUN and creatinine	1	1	Acute renal failure secondary to bilateral renal artery stenosis; treated medically with no further sequelae reported.
Replacement of RA lead during initial implant procedure	1	1	Replacement of RA lead due to helix extension mechanism failure during initial implant procedure.
Respiratory related events	5	8	Reports of pneumonia, cough, bronchitis, or wheezing treated medically; no further sequelae.
Shocks delivered for SVT/Afib in ventricular fibrillation zone	4	5	Therapy delivery appropriate: device performed as programmed (SVT discrimination not available to be programmed in Fib zone).
Shocks for MTD/MTF during SVT episode	2	2	Therapy delivery appropriate: device and features performed as Programmed. 1 pt. was re-programmed and 1 pt. prescribed amiodarone therapy.
Sinus bradycardia observed	3	3	1 pt. resolved by device reprogramming pacing rate; 2 pts. did not require re-programming.

Table 2. Other Reported Events (continued)

Event Description	# of Patients	# of Events	Comments
Stroke/TIA	2	2	TIA in setting of continuous AF at 3 mos. post-op in 1 pt.; Mid-cerebral artery CVA in 1 pt.
Syncope/Pre-syncope/Dizziness/ Vasovagal/Hypotension	4	4	General clinical symptoms treated medically with IV fluids post-op (2 pts.) and rest (2 pts.); no further sequelae reported.
VF episode requiring multiple external shocks prior to Epic HF system implant	1	1	Ventricular fibrillation episode that occurred in the EP lab during initial implant procedure and reported as possibly associated with hypokalemia.
TOTAL	58*	87	

Table 2. Other Reported Events (continued)

* Some patients experienced more than one event, and therefore the number of patients is less than the number of events.

Potential Adverse Events

Potential adverse events associated with the use of transvenous leads include:

- Allergic reaction to contrast media
- Body rejection phenomena
- Cardiac/coronary sinus dissection
- Cardiac/coronary sinus perforation
- Cardiac tamponade
- Coronary sinus or cardiac vein thrombosis
- Death
- Endocarditis
- Excessive bleeding
- Hematoma/seroma
- Induced atrial or ventricular arrhythmias
- Infection
- Lead dislodgment
- Local tissue reaction; formation of fibrotic tissue
- Loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead
- Myocardial irritability
- Myopotential sensing
- Pectoral/diaphragmatic/phrenic nerve stimulation
- Pericardial effusion
- Pericardial rub
- Pneumothorax/hemothorax
- Prolonged exposure to fluoroscopic radiation
- Pulmonary edema
- Renal failure from contrast media used to visualize coronary veins
- Rise in threshold and exit block
- Thrombolytic or air embolism
- Valve damage.

Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks.

Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely death.

Clinical Studies

The Aescula™ 1055K lead was evaluated in both the PAVE and RHYTHM ICD clinical studies.

PAVE Clinical Study

The Left Ventricular-Based Cardiac Stimulation Post AV Node Ablation Evaluation (PAVE) trial, a prospective, randomized, controlled, multi-center clinical trial conducted at 49 participating sites (44 in the US, 5 in Canada), compared the safety and effectiveness results for patients receiving the Frontier Model 5508 pulse generator and the Aescula 1055K Left Heart Lead to those receiving legally marketed right ventricular pulse generators and standard leads following an AV node ablation for chronic atrial fibrillation. Chronic AF is defined as persisting without interruption for at least one month. The study's cumulative implant duration was 4,684 months with a mean of 13.0 ± 9.6 months (range of 0.1 to 35.7 months). Two hundred and six (206) patients underwent successful LV lead placement. The cumulative duration in BV, LV and Roll-in groups was 3,129 months.

For this randomized study, the key inclusion criteria were:

- Patients who underwent complete AV node ablation for chronic atrial fibrillation (defined as persisting without interruption for at least one month) resulting in complete AV block,
- Patients who were on a stable medical therapy regimen, and
- Patients who were able to complete the six-minute walk with the only limiting factor(s) being fatigue and/or shortness of breath.

Key study exclusion criteria were:

- Patients who were classified as NYHA Class IV,
- Patients who could walk more than 450 meters in a six-minute walk test,
- Patients who had an implanted ICD or were considered for implant of an ICD,
- Patients with prosthetic valve replacements,
- Patients with severe musculoskeletal disorder(s), and
- Patients who could not independently comprehend and complete the quality of life questionnaire.

The overall study population included 361 patients. One hundred and forty-six (146) were randomized to BV and 106 were randomized to RV. In addition, 53 were randomized to LV pacing under a previous revision of the investigational plan. Fifty-six (56) were "roll-in" patients (non-randomized) and received the biventricular pacing system (Frontier pulse generator and Aescula lead system). All patients underwent implantation of a permanent pacemaker following an elective AV node ablation for chronic atrial fibrillation. The mean age was 69.23 ± 9.98 years and the population was 34.3% female and 65.7% male. Fifteen percent (15%) of the patients had no heart failure symptoms or were NYHA Class I, 48% were NYHA Class II, and 37% were NYHA Class III prior to implant. Safety data from all patients who underwent an attempted implant were reported.

Study Results

There were three primary safety objectives related to the Aescula Model 1055K Left Heart Lead. The results are outlined below.

Primary Objectives

1. Freedom from Aescula lead-related complications through six months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from Aescula lead related compli-

cation for the BV group through six months will not be less than 75%.

Results: There were 25 Aescula lead related complications in 24 patients through 6-months follow-up. The freedom from Aescula lead related complications was 88.2% with a lower bound of 84.4%. Table 3 outlines the Aescula lead related complications during the trial and all implant dissection and perforation events. A complication is an adverse event that was resolved invasively or resulted in the termination of the procedure, while an observation is an adverse event that was resolved without invasive procedures.

Event	BV, LV, and Roll-In (N = 254)*			
	# of Events	# of Patients	% of Patients	Events/ Device-Months†
LV Lead Related	25	24‡	9.4	0.0080
Acute LV Lead Dislodgement	9	9	3.5	0.0029
Diaphragmatic Stimulation	6	6	2.4	0.0019
High LV Pacing Threshold at Implant, Later System Revised	6	6	2.4	0.0019
LV Lead Loss of Capture	3	3	1.2	0.0010
Pectoral Stimulation	1	1	0.4	0.0003
Implant Dissection and Perforation Complications	11	10‡	3.9	0.0035
CS Dissection at Implant	7	6	2.4	0.0022
CS Perforation at Implant	3	3	1.2	0.0010
Cardiac Tamponade at Implant	1	1	0.4	0.0003

Table 3. Aescula lead-related complications and implant dissection and perforation events

* Aescula lead-related complications based on total number of procedures (N = 254).

† Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in BV, LV, and Roll-in group. The cumulative duration in months in these groups was 3,129 months.

‡ One patient may have more than one event.

Note: Three additional events of CS Dissection at Implant in three patients were classified as observations.

2. Rate of successful implantation of the Aescula lead

Objective: The lower bound of the one-sided 95% confidence interval of the successful implantation rate of the Aescula lead for the BV group will not be less than 80%.

Results: One hundred and forty-six (146) patients randomized to BV underwent attempted implants. One hundred and twenty-five (125) were successfully implanted. The rate of successful implant of the Aescula lead was 86% with a lower bound of 81%.

3. Aescula lead pacing threshold at 6-months

Objective: The upper bound of the one-sided 95% confidence interval of the mean capture threshold will not be greater than 3.0 V for the BV group at 6-months

Results: The pacing threshold at 6-months for the BV group was 2.27 V ± 1.66 V with an upper bound of 2.53 V.

RHYTHM ICD Clinical Study

The objective of the RHYTHM ICD clinical study was to verify the safety and efficacy of

the Epic HF ICD (Model V-338) system, including the Aescula Model 1055K lead, in an ICD indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration.

As of October 31, 2003, 205 patients were enrolled at 50 clinical sites in the RHYTHM ICD clinical investigation. The first Epic HF V-338 and Aescula 1055K left ventricular lead system was implanted on July 8, 2002.

As of March 17, 2004, the total time of follow-up from the time of successful implant was 2205 patient months. The average time of follow-up was 12.1 ± 3.4 (range 0.3 to 20.3) patient months.

Of the 205 patients enrolled in the RHYTHM ICD study, 175 patients were attempted with the Aescula 1055K lead. One hundred fifty-five (155) had successful lead implants.

One patient had a successful left ventricular lead implant, but had high defibrillation thresholds. This patient was withdrawn from the study and received a heart transplant, leaving a total of 154 successful system implants. Table 4 has a breakdown of the reasons for the 21 unsuccessful system implants.

Reason	# of Patients
LV Lead Related	
Unable to Cannulate the CS	5
Unable to Obtain Distal Placement	6
Unable to Obtain Stable Lead Position	3
High Pacing Thresholds	3
CS Dissection	3
Other	
High Defibrillation Threshold	1
Total	21

Table 4. Unsuccessful Implants (N = 21)

For this randomized study, the key inclusion criteria were:

- Approved indication for implantation of an ICD for treatment of a life-threatening ventricular tachyarrhythmia(s).
- Symptomatic, advanced heart failure (ischemic or non-ischemic) not due to reversible causes, diagnosed for at least 6-months.
- New York Heart Association (NYHA) Classification of III or IV, despite receiving a minimum of 90 days of appropriate pharmacological therapy which has been stable during the 30 days prior to enrollment.
- Left ventricular ejection fraction (LVEF) ≤ 35%.
- Ventricular conduction delay manifested as a QRS duration ≥ 150 msec.

Key study exclusion criteria were:

- Standard bradycardia indication for pacing.
- History of chronic atrial fibrillation (continuous AF lasting > 1 Month) within 1 year prior to enrollment or have undergone cardioversion for AF in the past month.
- Ability to walk > 450 meters during the 6-Minute walk test.
- Classification of Status 1 for cardiac transplantation or consideration for transplantation over the next 6-months.
- Recent myocardial infarction, unstable angina or cardiac revascularization (PTCA or CABG) within 1 month of enrollment.
- Recent CVA or TIA - within 3 months of enrollment.

Study Results

There were three safety objectives related to the Aescula Model 1055K Left Heart Lead. The results are below.

LV Lead-Related Complications (at 6 Months)

Table 5 summarizes the Aescula Model 1055K LV Lead Related Complications at 6 months. One hundred and fifty-five (155) patients who had a successful 1055K LV lead implant were analyzed for this endpoint. A total of 11 patients experienced 13 1055K LV lead-related complications.

The survival from 1055K lead related complications at 6-months was calculated as 92.8% with a 95% lower confidence bound of 89.4%, which is greater than the objective performance criteria of 75%.

Description of Complication	# of Events	# of Patients	% of Patients	Events/ Device-Months*
Diaphragmatic/Phrenic Nerve Stimulation	3	3	1.5%	0.0013
Lead Dislodgment or Migration	9	8	3.9%	0.0040
Elevated Pacing Threshold	1	1	0.5%	0.0004
LV Lead Related	13	11†	5.4%	0.0058

Table 5. Aescula 1055K LV Lead Related Complications

* Events per Device-Month calculated as number of events divided by the total patient follow-up duration in months (2,233 months).

† One patient experienced both a lead dislodgment/migration and diaphragmatic stimulation, and one patient experienced two lead dislodgments/migrations.

Aescula LV Lead Implant Success

Of the 175 patients who were attempted with the Aescula 1055K lead, 155 patients, or 88.6% had a successful implant. The 95% lower confidence bound on the percent successful implant was 83.8%, which is greater than the pre-specified objective performance criteria of 80%.

Aescula LV Lead Pacing Capture Threshold at 6-months

Table 6 displays the summary statistics for the data collected at the 6 month visit.

	LV Capture Threshold
N	140
Mean ± SD	2.2 ± 1.5
Range	(0.25, 7.5)

Table 6. Aescula 1055K LV Lead Capture Threshold

The 95% upper confidence limit for the mean LV lead capture threshold at 6 months was 2.37 V, which was less than the objective performance criteria of 3 V.

Conformance to Standards

The lead complies with IS-1 connector standard ISO 5841-3.

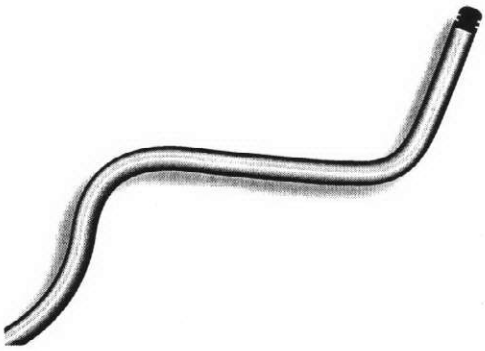
How Supplied

The Model 1055K Lead is packaged one per package in a sterile package. Each package contains:

- One passive-fixation pacing lead with suture sleeve attached
- One vein lifter
- One funnel
- Six (6) 0.014" stainless steel stylets with colors designating the degree of firmness:
  - 2 extra-firm stylets with 0.010" taper (red)

ST. JUDE MEDICAL

USER'S MANUAL

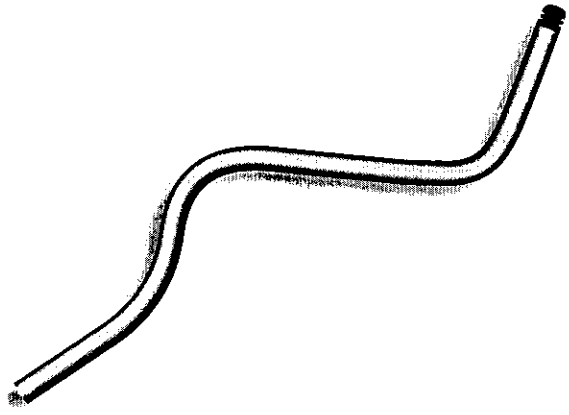


QuickSite®
Model 1056K

**Unipolar, Steroid-Eluting,
Titanium Nitride Electrode,
Guidewire/Stylet-Placed
Left Heart Lead
with Fast-Pass™ Coating**

User's Manual

ST. JUDE MEDICAL



QuickSite®
Model 1056K

**Unipolar, Steroid-Eluting,
Titanium Nitride Electrode,
Guidewire/Stylet-Placed
Left Heart Lead
Fast-Pass™ Coating**

User's Manual

CAUTION
Federal (USA) law restricts this device to sale by or on order of a physician.

TABLE OF CONTENTS

DESCRIPTION

The QuickSite® Model 1056K lead is a unipolar left heart lead with a Titanium Nitride (TiN) coated platinum/iridium electrode tip, designed for use with St. Jude Medical® implantable pulse generators with ventricular resynchronization therapy for long-term cardiac pacing and sensing. The lead can be positioned in an appropriate left-heart pacing site using either stylet placement or "over-the-wire" guidewire placement.

The lead's construction includes a long polyurethane-insulated proximal section and a short silicone-insulated distal section. A hole through the lead's tip electrode allows the use of a guidewire.

The distal section of the lead is preshaped into an "s-curve" to provide stabilization when the lead is placed through the coronary sinus into the veins overlying the ventricle.

The maximum lead body outer diameter is 6.0 French. The lead's connector complies with the IS-1 connector standard ISO 5841-3: 2000.

Features of the QuickSite Model 1056K Left Heart Lead include:

- Steroid Elution — an amount less than one milligram of dexamethasone sodium phosphate (DSP) is slowly released through the tip electrode upon contact with body fluid. The drug is intended to promote low acute and chronic stimulation thresholds by suppressing the local inflammatory response to a foreign body.
- Passive Fixation — incorporating an s-shaped curve designed to stabilize the lead in the coronary vein.
- Fast-Pass™ coating — creates a lubricious surface.

INDICATIONS/INTENDED USE

The QuickSite® Model 1056K lead has application as part of a St. Jude Medical® biventricular system.

CONTRAINDICATIONS

The use of QuickSite leads is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate
- Are unable to undergo an emergency thoracotomy procedure
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

PACKAGE CONTENTS

The lead comes in a box containing three separate packages. The contents of each package are sterile.

The lead package contains:

- One QuickSite Model 1056K passive-fixation left heart lead with radiopaque suture sleeve attached
- One vein pick
- One lead flushing tool.

The stylet package contains:

- Six (6) stainless steel ball-tipped PTFE-coated stylets with a 15 cm taper. Button colors designate the degree of firmness:
  - 1 extra-firm stylet (red button) with the taper to 0.25 mm (0.010 in.)
  - 2 firm stylets (yellow button) with the taper to 0.20 mm (0.008 in.)
  - 3 soft stylets (green knob) with 15 cm taper to 0.15 mm (0.006 in.).

The guidewire package contains:

- One 180 cm PTFE-coated 5 cm floppy-tip guidewire
- Two (2) Torque tools.

Additional stylet and guidewire accessory kits are also available individually for this lead.

Lead Packaging

Check the "use-before" date on the package label. Do not implant a lead if its "use-before" date has expired.

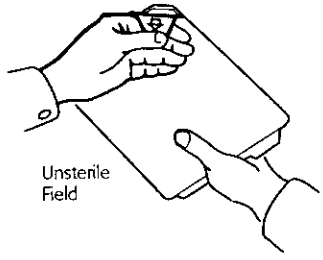


Figure 1. The outer tray cover may be peeled back by a person not prepared for the sterile field.

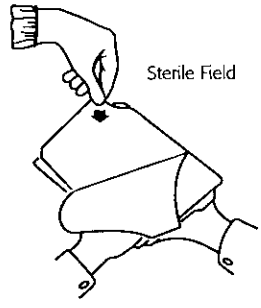


Figure 2. Only a person prepared for the sterile field may open the inner tray.

Opening the Inner Tray

In order to preserve sterility, operating room procedures should be followed when opening the inner tray.

Caution

Avoid bringing the lead into contact with any sharp object which could puncture or otherwise damage the insulation. Avoid handling the lead with surgical tools.

Storage

- Store the lead at temperatures between -5° C (23° F) and 50° C (122° F).
- The lead package has been sterilized with ethylene oxide for direct introduction of the inner tray into the surgical field.
- Do not implant the lead if the sterility indicator dot within the inner package is purple, because it may not have been sterilized.
- Before the package is opened, inspect it visually for any damage that may have compromised sterility.

Sterilization Instructions

- For single use only.
- Do NOT sterilize the lead using an autoclave, gamma radiation or ultrasonics.
- Do not resterilize the lead more than once.

If resterilization is necessary, place the lead and accessories in a gas-permeable package and resterilize in ethylene oxide. The sterilizer temperature should not exceed +50° C (122° F). After sterilization, allow sufficient time for the complete aeration of ethylene oxide residuals prior to implantation.[1] This process may be shortened by forced ventilation. Use biological controls to verify the effectiveness of the resterilization.

1. See also AAMI GVR-1987, *Good Hospital Practice: Ethylene Oxide Gas–Ventilation Recommendations and Safe Use.*

Warnings and Precautions

Lead Selection

- Before opening the lead package, confirm that the lead is compatible with the pulse generator to be implanted.

Storage and Handling

- For single use only.
- Do not sterilize the lead using an autoclave, gamma radiation, or ultrasonics; if sterilization is required, see page 2.
- Do not stretch, crush, kink or bend the lead. Leads may be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- Do not bring the lead into contact with sharp objects which could puncture or otherwise compromise the insulation.
- Handle the lead only with powderless, sterile surgical gloves.
- Avoid handling the lead with surgical tools such as hemostats, clamps or forceps.
- Carefully check that the suture sleeve moves freely before implantation.
- Leads have an electrostatic attraction for particulate matter; do not expose them to lint, dust or other such materials.
- Do not touch or handle the lead's tip electrode.
- Do not immerse the lead body, stylets, or guidewires in mineral oil, silicone oil or any liquid other than sterile saline or sterile water.
- Do not immerse the tip electrode in any fluid prior to implantation.

Lead Evaluation and Testing

- Exercise extreme caution when testing leads.
- Use only battery-powered equipment during lead implantation and testing to protect against fibrillation which may be induced by alternating current.
- Use only properly grounded line-powered equipment in the vicinity of the patient during the implant procedure.
- Isolate the lead connector pin from any leakage currents that may arise from line-powered equipment.

Lead Implantation

- Lead implantation should be performed only when proper emergency facilities for cardioversion and/or defibrillation are available.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- During this procedure it is advisable to also have echocardiographic equipment available.
- Use only the ball-tipped stylets packaged with the lead or in the accompanying accessory kits. Other stylets may extend beyond the lead tip causing lead tip damage and/or patient injury.
- Do not use excessive force when inserting the stylet or guidewire into the lead.
- Use only appropriate diameter (0.36mm or 0.014in) and length (at least 180 cm) guidewires.
- Do not flush the lead's lumen with any liquid other than sterile saline or sterile water.
- If subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.
- Failure to use the suture sleeve to secure the lead may result in lead dislodgment or in damage to the lead's insulation and/or conductor.

ADVERSE EVENTS

The RHYTHM ICD/QuickSite Lead study was a prospective, multi-center investigation designed to evaluate the safety and effectiveness of the QuickSite left ventricular lead system in patients who were indicated for implantable cardioverter defibrillation therapy with New York Heart Association Class III/IV heart failure and a prolonged QRS duration.

Per the investigational plan, an *adverse event* is defined as any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a clinical study participant caused by or associated with a study device or intervention. Adverse events were classified as complications or observations based on the following definitions:

- *Complications* are defined as adverse events that require invasive intervention (for example, lead dislodgment requiring repositioning).
- *Observations* are defined as adverse events that can be managed without invasive intervention (for example, oversensing or loss of pacing capture, which is then remedied by reprogramming of the pulse generator).
- *Other Reported Event* is defined as any other clinical event that was reported by the investigator, which is not an adverse event as defined above.

Observed Adverse Events

Table 1 lists the observations and complications reported from the RHYTHM ICD/QuickSite Lead clinical trial (see *Clinical Study* on page 7). A total of 45 adverse events have been reported in 37 of 162 patients (22.8%). Sixteen patients (9.9%) experienced complications and 24 patients (14.8%) experienced observations.

Event Description	Number of Patients with AEs* (N = 162)	% of Patients with AEs	Number of AEs	AE/pt-years (N = 94.53 Years)
Complications (total)	**16**	**9.9%**	**18**	**0.190**
Bleeding/Hematoma	1	0.6%	1	0.011
Diaphragmatic/Phrenic Nerve Stimulation – LV Lead	5	3.1%	6	0.063
Elevated Pacing Thresholds – LV Lead	1	0.6%	1	0.011
Infection	2	1.2%	2	0.021
Lead Dislodgment or Migration – LV Lead	1	0.6%	1	0.011
Lead Dislodgment or Migration – RA Lead	2	1.2%	2	0.021
Pericardial Effusion	1	0.6%	1	0.011
Pocket Non-Approximation	1	0.6%	1	0.011
Respiratory Arrest Requiring Ventilatory Support	1	0.6%	1	0.011
Suspected Generator Malfunction	2	0.12%	2	0.021
Observations (total)	**24**	**14.8%**	**27**	**0.286**
Bleeding/Hematoma	6	3.7%	6	0.063
Cardiac Vein Thrombus	1	0.6%	1	0.011

Table 1. RHYTHM ICD/QuickSite Lead Adverse Events

Event Description	Number of Patients with AEs* (N = 162)	% of Patients with AEs	Number of AEs	AE/pt-years (N = 94.53 Years)
Diaphragmatic/Phrenic Nerve Stimulation – LV Lead	9	5.6%	9	0.095
Diaphragmatic/Phrenic Nerve Stimulation – RV Lead	1	0.6%	1	0.011
Elevated Pacing Thresholds - LV Lead	5	3.1%	5	0.053
Elevated Pacing Thresholds – RV Lead	1	0.6%	1	0.011
Inappropriate Therapy (ATP) for SVT	1	0.6%	1	0.011
Inappropriate Therapy (Shock) for SVT	1	0.6%	1	0.011
Insulation Damage to RA Lead	1	0.6%	1	0.011
Post-Operative Shoulder Pain	1	0.6%	1	0.011

Table 1. RHYTHM ICD/QuickSite Lead Adverse Events (continued)

* Some patients experienced more than one observation and/or complication and therefore the number of patients is less than the number of events.

Table 2 contains a summary of all Other Reported Events, along with a brief description of each.

Event Description	Number of Patients	Number of Events	Comments
Bacteremia	1	1	Gram positive bacteremia, unrelated to implant procedure; treated with antibiotics.
Chest pain/tightness	5	5	ER/hospitalizations for complaints of chest pain; all treated medically.
Inflammatory response/ swelling/elevated WBCs	3	3	General clinical symptoms evaluated and treated medically with prophylactic antibiotics; no further sequelae.
Elective surgery	1	1	Cholecystectomy.
Occasional noise noted on electrogram	1	1	Noise observed on atrial channel of stored electrogram; device re-programming was not required.
Pericarditis	2	2	Treated medically with NSAIDs; no further sequelae.
Respiratory related events	4	4	COPD exacerbation in 1 patient treated medically;1 patient with upper respiratory infection treated medically; 2 patients with pneumonia treated medically.
Shocks delivered for SVT/Afib in ventricular fibrillation zone	2	2	Therapy delivery appropriate: device performed as programmed (SVT discrimination not available to be programmed in Fib zone).

Table 2. Other Reported Events

Event Description	Number of Patients	Number of Events	Comments
Sinus bradycardia observed	1	1	Resolved by device reprogramming of pacer rate.
Dizziness/Hypotension/ Syncope	4	4	One patient developed hypotension post-op associated with rapid AF treated with IV fluids and later required diuretics for volume overload; 1 pt with orthostasis responded to decrease in diuretic dosage; 1 patient with low blood pressure treated with BV pacing; 1 patient with recurrent syncope due to hypotension was treated with IV fluids.
Shortened AV delay caused by frequent PVCs	1	1	AV delay re-optimized by device reprogramming.
Digoxin toxicity	1	1	Digoxin dose adjusted; no further sequelae.
Stroke/TIA	1	1	Left upper extremity weakness later diagnosed as stroke.
Pacing sensation/palpitation	1	1	Palpitations associated with ventricular ectopy.
Inappropriate mode switches	1	1	Far-R suppression interval adjusted.
T-wave sensing not resulting in therapy	1	1	Resolved by reprogramming.
Total	**30**	**30**	

Table 2. Other Reported Events (continued)

Nine patients (5.6%) enrolled in the RHYTHM ICD/QuickSite Lead clinical investigation were withdrawn from the study due to death. A summary of the Events Committee death classifications is shown in Table 3. None of the deaths were lead-related.

Primary Cause	Total
Cardiac-Arrhythmic	1
Cardiac-Nonarrhythmic	4*
Cardiac-Unknown	0
Non-Cardiac	1
Unknown	3
Total	**9**

Table 3. Events Committee Classification of Patient Deaths

* One patient died after undergoing an unsuccessful QuickSite lead implantation. This death was unrelated to the implant procedure.

Potential Adverse Events

Potential adverse events associated with the use of transvenous leads include:

- Allergic reaction to contrast media
- Body rejection phenomena
- Cardiac/coronary sinus dissection
- Cardiac/coronary sinus perforation
- Cardiac tamponade
- Coronary sinus or cardiac vein thrombosis
- Death
- Endocarditis
- Excessive bleeding
- Hematoma/seroma
- Induced atrial or ventricular arrhythmias
- Infection

- Lead dislodgment
- Local tissue reaction; formation of fibrotic tissue
- Loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead
- Myocardial irritability
- Myopotential sensing
- Pectoral/diaphragmatic/phrenic nerve stimulation
- Pericardial effusion
- Pericardial rub
- Pneumothorax/hemothorax
- Prolonged exposure to fluoroscopic radiation
- Pulmonary edema
- Renal failure from contrast media used to visualize coronary veins
- Rise in threshold and exit block
- Thrombolytic or air embolism
- Valve damage.

Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks.

Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely, death.

CLINICAL STUDY

The RHYTHM ICD/QuickSite Lead study was a prospective, multi-center investigation designed to evaluate the safety and effectiveness of the QuickSite left ventricular lead system in an ICD-indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration.

Primary Objective

The primary objective of the study was to evaluate the safety and effectiveness of the QuickSite lead.

- Safety of the QuickSite left heart lead was evaluated in terms of survival from LV lead-related complications at three months.
- Efficacy of the QuickSite left heart lead was determined by the LV lead implant success rate and ventricular pacing threshold at three months.

Clinical Study Results

As of December 3, 2003, 162 patients were enrolled at 49 clinical sites in the RHYTHM ICD/QuickSite Lead clinical investigation. The first QuickSite 1056K lead was implanted on March 26, 2003. As of March 17, 2004, the total time of follow-up from the time of successful implant was 1127 patient months. The average time of follow-up was 7.3 ± 2.0 (range 0.1 to 11.7) patient months.

The patient inclusion criteria were:

- Approved indication for implantation of an ICD for treatment of a life-threatening ventricular tachyarrhythmia(s)
- Symptomatic heart failure with a New York Heart Association (NYHA) Classification of III or IV, despite optimal pharmacological therapy
- Left ventricular ejection fraction (LVEF) $\leq 35\%$
- Ventricular conduction delay manifested as a QRS duration ≥ 130 msec
- Willingness and ability to provide informed consent for study participation and to comply with the prescribed follow-up tests and schedule of evaluations.

The patient exclusion criteria were:

- NYHA Classification of I or II

- Contraindication for an emergency thoracotomy
- Hypersensitivity to a single 1.0 mg dose of dexamethasone sodium phosphate
- Classification of Status 1 for cardiac transplantation or consideration for transplantation over the next three months
- Recent myocardial infarction, unstable angina or cardiac revascularization (PTCA, Stent or CABG) within 30 days of enrollment
- Current participation in a clinical investigation that includes an active treatment arm
- Pregnancy or planning for pregnancy in the next six months
- Life expectancy of less than six months
- Less than 18 years of age.

Table 4 contains a summary of the pre-implant assessment information on all patients included in the QuickSite Left Heart Lead study patient cohort (162 patients).

Demographic variable	Overall group (N = 162)
Age (years):	
Mean ± SD	68.8 ± 9.9
Range	(39, 86)
Gender, n (%):	
Male	132 (81.5%)
Female	30 (18.5%)
NYHA Class, n (%):	
III	149 (92%)
IV	13 (8%)
LV Ejection Fraction (%):	
Mean ± SD	22.5 ± 6.7
Range	(10, 35)
QRS duration (ms):	
Mean ± SD	166 ± 21
Range	(130, 240)
Cardiomyopathy Classification:	
Ischemic, n (%)*:	**126 (77.8%)**
Myocardial Infarction	119 (94.4%)
CABG	86 (68.3%)
PTCA	57 (45.2%)
Unstable Angina	42 (33.3%)
Non-Ischemic, n (%):	**36 (22.2%)**
Idiopathic	19 (52.8%)
Hypertensive	6 (16.7%)
Familial/Congenital	2 (5.6%)
Alcoholic	4 (11.1%)
Valvular	2 (5.6%)
Other	3 (8.3%)

Table 4. Pre-Implant Assessment Information

Demographic variable	Overall group (N = 162)
Other Medical History, n (%)*:	
Hypertension	99 (61.1%)
Diabetes	59 (36.4%)
COPD	36 (22.2%)
Other	115 (71.0%)
None	13 (8.0%)
Intrinsic Ventricular Conduction, n(%):	
LBBB	112 (69.1%)
RBBB	27 (16.7%)
IVCD	23 (14.2%)
Primary Indication for ICD, n (%):	
VT	25 (15.4%)
VF	7 (4.3%)
VT and VF	11 (6.8%)
Primary Prevention	64 (39.5%)
Upgrade	44 (27.2%)
Syncope	5 (3.1%)
Did not have Class I/II indication	6 (3.7%)
Pre-Implant Medications, n (%):	
ACE Inhibitors/substitutes	112 (69.1%)
Beta Blockers	131 (80.9%)
Angiotensin Receptor Blockers	31 (19.1%)
Diuretics	150 (92.6%)
Positive Inotropics/Glycoside	95 (58.6%)
Nitrates	54 (33.3%)
Anti-Coags and Anti-Platelets	145 (89.5%)
Calcium Channel Blockers	8 (4.9%)
Anti-Arrhythmics	45 (27.8%)

Table 4. Pre-Implant Assessment Information (continued)

* Individual patients may be included in more than one subcategory.

Of the 162 patients enrolled in the RHYTHM ICD/QuickSite Lead study, 153 lead implant attempts were successful. Table 5 has a breakdown of the reasons for the nine unsuccessful implants.

Reason	# of Patients	% of Total Patients
LV Lead-Related:		
Unable to Cannulate the CS	4	2.47%
Unable to Obtain Distal Placement	3	1.85%
Unable to Obtain Stable Lead Position	2	1.23%
Total	9	5.56%

Table 5. Unsuccessful Implants

Table 5. Unsuccessful Implants

Primary Objective Results

LV Lead-Related Complications at 3 Months

Table 6 summarizes the QuickSite Model 1056K LV lead-related complications at three months. One hundred and fifty-three patients who had a successful QuickSite 1056K LV lead implant were analyzed for this endpoint. A total of six patients experienced eight LV lead-related complications.

The survival from QuickSite 1056K LV lead-related complications at three months was calculated as 96.1% with a 95% lower confidence bound of 93.5%, which is greater than the objective performance criteria of 80%.

Description of Complication	# of Events	# of Patients	% of Patients*
Diaphragmatic/ Phrenic Nerve Stimulation	6	5	3.27%
Elevated Pacing Thresholds	1	1	0.65%
Lead Dislodgment or Migration	1	1	0.65%
Total	8	6†	3.92%

Table 6. QuickSite 1056K LV Lead-Related Complications

* Percentage of patients with successful implants experiencing lead-related complications.

† One patient experienced two Diaphragmatic Stimulation events, and one patient had one Diaphragmatic Stimulation event and one Lead Dislodgment event.

Survival From All Complications at 3 Months

In addition to the protocol-specified QuickSite LV lead-related complication endpoint, survival from all complications at three months, including procedural complications and patients with unsuccessful implants, was analyzed following a review of the clinical results.

One hundred and sixty-two patients who had attempted implants with the QuickSite 1056K LV lead were included in this analysis. Table 7 lists all complications experienced by each patient. A total of 16 patients experienced 18 complications.

The survival from all complications at three months was calculated as 90.6% with a 95% lower confidence bound of 86.7%.

Description of Complication	Number of Events	Number of Patients
Bleeding/Hematoma	1	1
Diaphragmatic/ Phrenic Nerve Stimulation	6	5
Elevated Pacing Thresholds	1	1
Infection	2	2
Lead Dislodgment or Migration – LV Lead	1	1
Lead Dislodgment or Migration – RA Lead	2	2
Pericardial Effusion	1	1
Pocket Non-approximation	1	1
Respiratory Failure Requiring Ventilatory Support	1	1
Suspected Generator Malfunction	2	2
Total	18	16*

Table 7. All Complications

* One patient experienced two Diaphragmatic Stimulation events, and one patient had one Diaphragmatic Stimulation event and one Lead Dislodgment event.

QuickSite LV Lead Implant Success

Of the 162 patients who were attempted with the QuickSite 1056K lead, 153 patients, or 94.4%, had a successful LV lead implant. The 95% lower confidence bound on the percent successful implant is 90.5%, which is greater than the objective performance criteria of 80%.

QuickSite LV Lead Pacing Capture Threshold at 3 Months

Table 8 displays the summary statistics for the pacing capture threshold data collected at the three month visit.

	LV Capture Threshold
N	139
Mean ± SD	1.6 ± 1.4
Range	(0.25, 7.5)

Table 8. QuickSite 1056K LV Lead Capture Threshold (V)

The 95% upper confidence limit for the mean LV lead capture threshold at three months is 1.81 V, which is less than the objective performance criteria of 3 V.

Conformance to Standards

QuickSite 1056K leads comply with the international IS-1 connector standard ISO 5841-3: 2000.

Clinician Use Information

Physician Training

Before using this lead, you must have completed St. Jude Medical's training program or have equivalent experience obviating the need for training. Physicians should be familiar with the placement of left-heart pacing leads, sterile implant procedure and follow-up evaluation.

The following sections describe various stages of lead implantation. Procedures included in these sections are only recommendations. Actual implant procedures are left to the discretion of the implanting physician.

Directions for Use

Lead Preparation

It is important that the implanting physician completely understand the mechanical operation of this lead before surgery.

An appropriate catheter delivery system should be used to facilitate the insertion of the lead into the coronary sinus vasculature.

Lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer(s) prior to implantation.

Lead Introduction

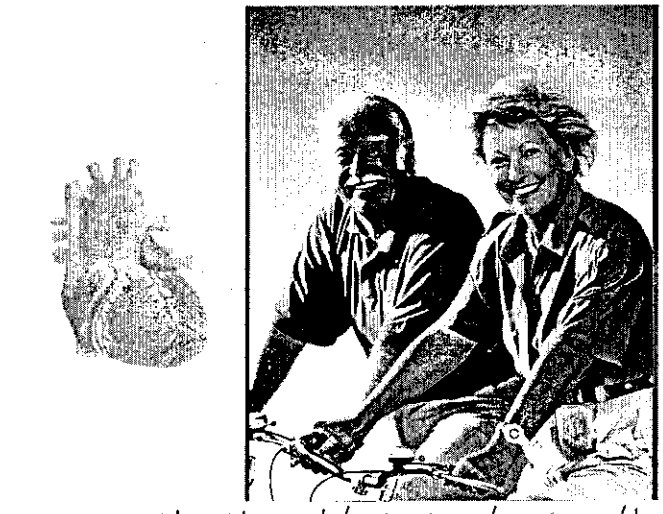
Selecting and Accessing a Vein

One suggested entry site is the left cephalic vein entered via an appropriate catheter delivery system for coronary sinus lead introduction.

Alternatively, the lead may be implanted via the left subclavian vein, also using an appropriate catheter delivery system for coronary sinus lead introduction. However, studies[2,3] indicate that the incidence of lead damage may be decreased with the lead placed by cephalic vein cutdown.

If subclavian entry via an appropriate catheter delivery system for coronary sinus lead introduction is chosen, choose a puncture site as lateral as possible (in the area under the lateral two-thirds of the clavicle, lateral to the subclavius muscle). The right subclavian vein and the internal jugular vein may also be used, if necessary.

2. Magney, J.E., Flynn, D.M. Parsons, J.A., et al.: Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads, and Failure of Central Venous Catheters Adjacent to the Sternoclavicular Joint. PACE 16 (I): 445-457, 1993.
3. Jacobs, D.M., Fink, A.S., Miller, R.P., et al.: Anatomical and Morphological Evaluation of Pacemaker Lead Compression. PACE 16 (I): 434-444, 1993.



A Patient's Guide to Understanding Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

ST. JUDE MEDICAL

St. Jude Medical thanks James G. Porterfield, M.D., and Linda M. Porterfield, Ph.D., Arrhythmia Consultants, Methodist Central Hospital and University of Tennessee, Memphis, for their contribution to this booklet, parts of which are based on their interactive computer-disk program, *Know Your Defibrillator.*

Your Contact and Device Information

Have your doctor or nurse complete the information on these pages before you go home from the hospital.

Physician Name _____

Phone Number _____

Address _____

_____

Hospital Name _____

Phone Number _____

Address _____

_____

Device Model Number _____

Serial Number _____

Date Implanted _____

Description _____

_____

_____

_____

_____

_____

Physician Instructions

Living With Your Device

Many people suffer from heart disease. Often it takes the form of a rapid heartbeat that can result in a stopping of the normal pumping action of the heart (cardiac arrest). This kind of heartbeat is called an arrhythmia (a RITH me uh).

There are also some patients who have congestive heart failure or heart failure. Heart failure is a medical condition in which the heart muscle is weakened and can no longer pump blood as efficiently as a healthy heart.

Your doctor has explained that you have an arrhythmia and heart failure.

There are several ways to treat arrhythmias and heart failure. This booklet is about one of the treatments, implantation of a device called a cardiac resynchronization therapy defibrillator (CRT-D).

Implantable cardioverter-defibrillators (ICDs) look a lot like pacemakers. As you may already know, pacemakers can speed up a slow heartbeat. ICDs do just the opposite. They slow down a

too-rapid heartbeat. Some ICDs can do both. A CRT-D is an ICD that includes a pacing feature to help resynchronize (coordinate) the lower heart chambers, enabling your heart to beat efficiently.

When you have a CRT-D, there are certain things you need to know about.

Caution: Electromagnetic interference (EMI) may interfere with the function of your CRT-D. Avoid sources of electromagnetic fields. (Page 25)

Caution: Metal detectors and Electronic Article Surveillance (EAS) systems will not harm your CRT-D if you pass through the archway at a normal pace. Avoid lingering in the immediate area. If a search with a hand held wand is performed you should stress to security personnel that the search should be performed quickly and that they should avoid holding the wand over your CRT-D for a prolonged period. (Page 27)

Caution: Medical equipment, such as diathermy, TENs units, and MRI may affect the function of your device. Always tell the doctor or nurse that you

have a CRT-D before undergoing any medical procedure. (Page 28)

Caution: Keep a hand-held personal cellular phone at least 6 inches (15 cm) from your CRT-D. A cellular phone may affect the function of your device. (Page 31)

Detailed information is provided in *Cautions and Warnings* beginning on page 24 of this booklet.

CRT-Ds protect the lives of many people worldwide. You and your doctor may decide to use a CRT-D in your treatment. We at St. Jude Medical want you to feel comfortable about your decision, so we have provided you with this guide. It will help you understand how CRT-Ds work and how they will affect your life.

You will probably have questions that this booklet does not answer. We encourage you to discuss them with your doctor and your nurse. They are your partners in health care and your best source of information.

If you come across a word you do not understand, you can find its definition in the Glossary on page 47.

Table of Contents

The Healthy Heart

Why is the heart sometimes called a "pump"?

The heart's job is to move blood around the body. Blood contains the oxygen that the organs and tissues need to do their work. The blood cells pick up oxygen in the lungs and the pumping action of the heart moves this oxygen-rich blood to the rest of the body.

What does the heart look like?

As shown in Figure 1, the heart has four chambers. When it is at rest, the chambers fill with blood. With each heartbeat, the heart squeezes blood out into the body.

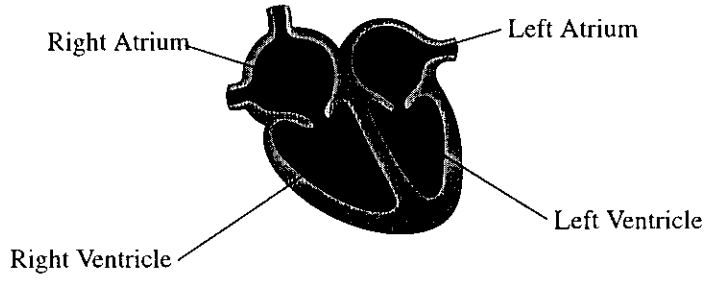


Figure 1. A typical heart.

How often does the heart beat?

A normal heart beats 60 to 100 times each minute.

When you exercise, get excited, or experience stress, your body needs more oxygen. Your heart beats faster to keep up with the demand. How fast it beats is controlled by a small area in the upper chamber of your heart. This area is called the sinoatrial (SA) node. It sends out an electrical signal that causes your heart to beat. Figure 2 shows the location of the SA node.

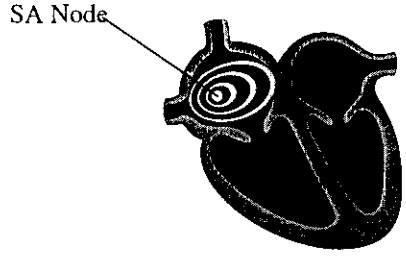


Figure 2. The sinoatrial (SA) node sends out an electrical signal that causes your heart to beat.

Arrhythmias

What is an arrhythmia?

An arrhythmia is any heart rhythm that is "abnormal." It may be considered abnormal if it is too fast, too slow or starts somewhere in the heart other than the SA node.

What causes the different kinds of arrhythmias?

Damage to the SA node or blockage of its electrical signal can cause the heart to beat too slowly. This is called *bradycardia.*

Bradycardia

A person with bradycardia may feel very tired because their body is not getting enough oxygen. They may also feel light-headed or dizzy. Pacemakers correct bradycardia by speeding up the heartbeat to a more normal rate.

Ventricular Tachycardia

Sometimes the heart beats much too fast. This is a serious condition called ventricular tachycardia (VT). As shown in Figure 3, VT is caused by signals that come from the heart's lower chamber instead of from the SA node. During VT, the heart beats so fast that its chambers can not completely fill with blood between beats. Therefore, less blood and oxygen are pumped through the body, causing dizziness, fainting, or loss of consciousness.

Doctors and paramedics can stop VT with medication or with an electrical shock. Sometimes the heart's normal rate returns without treatment.

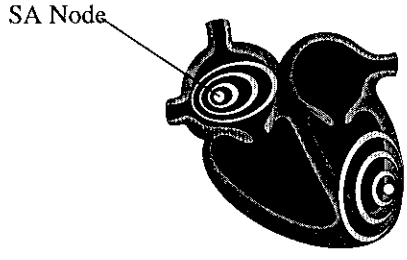


Figure 3. Ventricular tachycardia (VT) is caused by signals that come from the heart's lower chamber instead of from the SA node.

Ventricular Fibrillation

The most serious kind of arrhythmia is ventricular fibrillation (VF). As Figure 4 illustrates, during VF many, many electrical signals come from the heart's lower chambers. These signals cause the heart to "quiver" rather than beat normally. Because of the quivering, very little blood is pumped out to the body. A person suffering from VF loses consciousness very quickly. An electrical shock must be given at once to restore normal heart rhythm. This can be done by a CRT-D or an external defibrillator. Untreated ventricular fibrillation can be fatal.

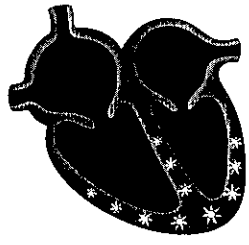


Figure 4. Ventricular fibrillation (VF) is caused by many electrical signals that come from the heart's lower chambers and cause the heart to quiver.

Heart Failure

What is heart failure?

Besides beating too fast or too slow, the heart can also beat irregularly. In some patients, one side of the heart may contract sooner than the other side. When this happens, the pumping mechanism begins to fail. Blood and oxygen are not delivered fast enough to the body. This condition is called heart failure.

What is congestive heart failure?

Fluid can also back up in the lungs and elsewhere in the body, causing congestion similar to a traffic jam. This fluid back up can lead to a serious condition called congestive heart failure.

These conditions are usually treated with drugs, but in some cases, a CRT-D can be used to help in the treatment. CRT-Ds can help the left and right ventricles beat at the same time (resynchronize the heartbeat).

Some Basic Facts About CRT-Ds

What is a CRT-D?

CRT-D stands for cardiac resynchronization therapy defibrillator. It is a special type of implantable cardioverter-defibrillator (ICD) that includes a pacing feature to help resynchronize (coordinate) the lower heart chambers, enabling your heart to beat efficiently.

Through the use of electronic circuitry, the battery-powered CRT-D senses the heart's rhythm and delivers treatment when necessary. This treatment is in the form of electrical pulses delivered to the heart. Wires, or "leads," connect the CRT-D to the heart. An illustration of a CRT-D and leads is shown in Figure 5.

A CRT-D is different from other ICDs. Typically, an ICD has either one or two leads in the right side of the heart. A CRT-D can have up to three leads: one in the right atrium, one in the right ventricle and one for the left ventricle.

A CRT-D can be used with your prescribed heart medications as part of your treatment plan.

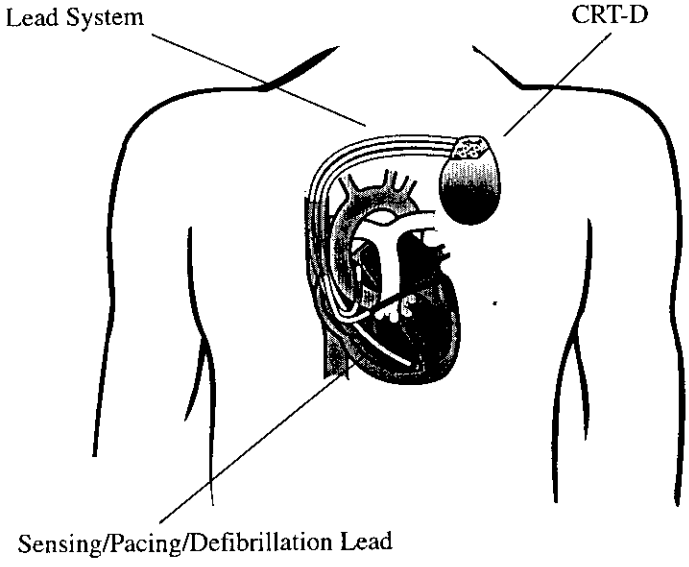


Figure 5. A CRT-D system.

What does a CRT-D do?

A CRT-D corrects rapid, abnormal heart rhythms. It constantly watches the heart and delivers treatment to stop an abnormally fast rate—such as VT and VF described on the previous pages. CRT-Ds can treat slow rhythms as well. They do this by sending tiny electrical impulses to the ventricle, the atrium, or both.

Your doctor sets the CRT-D to watch for heart rates that could be harmful to you. When the CRT-D senses that you are having an arrhythmia, it sends electrical pulses to the heart muscle through the leads. The electrical pulses slow the heart, therefore restoring a more normal rate.

To treat heart failure, the CRT-D monitors your heart signals and sends electrical pulses to the lower chambers of your heart and enables them to contract more efficiently.

Why do I need a CRT-D?

CRT-Ds are for people who are at risk of sudden cardiac death due to an abnormal ventricular arrhythmia. Your doctor has determined that despite taking medication for heart failure, you still have heart failure symptoms.

Who does not need a CRT-D?

If your conditions are reversible, temporary, or can be controlled solely by drugs or other methods, you do not need a CRT-D. If you are not taking medication for heart failure you should not receive a CRT-D. There is more about medication in a later section of this booklet.

What is the therapy like?

The electrical pulses that are delivered to your heart for heart failure and some arrhythmias are very small. You probably won't notice this kind of therapy.

Stopping other, very fast arrhythmias may require a larger pulse of energy (a shock). A shock has been described by some CRT-D patients as a swift thump or blow to the chest. How strong the thump feels depends on how strong the shock is. Lower energy shocks may produce a less intense thump. Any discomfort associated with shock therapy lasts for only a short time.

How often does the CRT-D deliver therapy?

To treat arrhythmias, therapy varies widely from patient to patient, depending on each patient's heart condition.

For heart failure, the purpose of the CRT-D is to deliver therapy when the lower chambers of the heart are not beating in synchrony. For the most part, this therapy is constant.

What should I do if I receive a shock?

Your doctor will tell you what to do if you receive a shock. Doctors usually want to know right away if you receive two or more shocks within 24 hours.

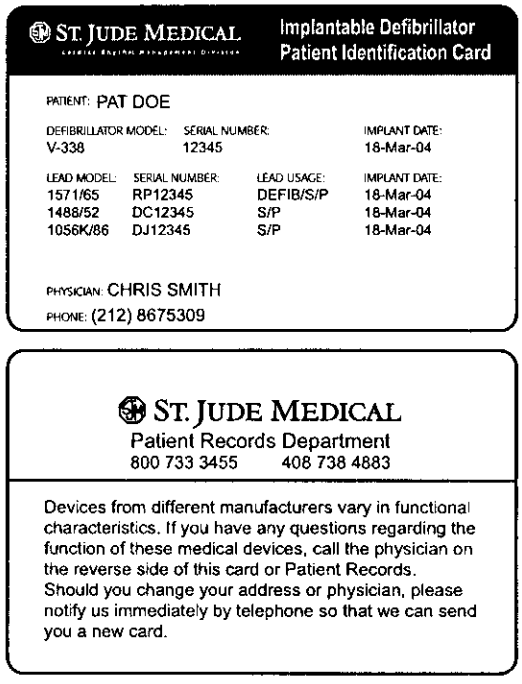
Important: Follow your doctor's instructions about what to do if you receive a shock.

When you receive a shock:

What happens after the CRT-D is implanted?

Your doctor will give you a special schedule to follow for your regular checkup visits. Checkups don't hurt and take only a few minutes. They tell the doctor if your CRT-D is working properly and how much energy is left in the battery. Checkups also tell how often your CRT-D has delivered electrical pulses to your heart.

After your CRT-D is implanted, you will be given an identification card with information about your CRT-D. Put the card in your wallet or carry it with you at all times. Show your card if you are ever in an emergency, are admitted to a hospital, see a new doctor or need to prove that you have a CRT-D.



ST. JUDE MEDICAL

Implantable Defibrillator
Patient Identification Card

PATIENT: PAT DOE

DEFIBRILLATOR MODEL:	SERIAL NUMBER:		IMPLANT DATE:
V-338	12345		18-Mar-04

LEAD MODEL:	SERIAL NUMBER:	LEAD USAGE:	IMPLANT DATE:
1571/65	RP12345	DEFIB/S/P	18-Mar-04
1488/52	DC12345	S/P	18-Mar-04
1056K/86	DJ12345	S/P	18-Mar-04

PHYSICIAN: CHRIS SMITH
PHONE: (212) 8675309

ST. JUDE MEDICAL
Patient Records Department
800 733 3455 408 738 4883

Devices from different manufacturers vary in functional characteristics. If you have any questions regarding the function of these medical devices, call the physician on the reverse side of this card or Patient Records.
Should you change your address or physician, please notify us immediately by telephone so that we can send you a new card.

Figure 6. Example of a typical St. Jude Medical Patient Identification Card.

You can obtain an application for a Medic Alert® identification emblem. The Medic Alert Foundation provides an ID emblem for people with medical problems. If you become ill and need emergency aid, the emblem alerts medical professionals that you have a

CRT-D. For more information, contact the Medic Alert Foundation at (209) 668-3333 (888-633-4298 in the USA).

What happens when the battery runs down?

CRT-Ds can be expected to last anywhere from three to seven years. The life of the CRT-D depends on how often it delivers therapy. When the battery gets low, the entire CRT needs to be replaced. An incision is made where your current CRT-D is located, and your current CRT-D will be replaced with a new one. This is generally a very quick procedure and you will probably stay in the hospital for only a short time. Your CRT-D can be replaced as many times as needed. During the CRT-D exchange, the lead wires are not usually changed, but they are tested to make sure they are still working properly.

What happens if a lead needs to be replaced?

If a lead needs to be replaced, surgery is required to replace it.

Risks and Benefits

What are the benefits of having a CRT-D?

The major benefit of a CRT-D is that it constantly senses the heart's rhythm and automatically treats an arrhythmia. If your arrhythmia is very dangerous, this treatment can save your life. Also, many patients find that symptoms such as light-headedness, dizziness, and fainting decrease after they get a CRT-D. Some patients no longer need anti-arrhythmia drugs, and others need less anti-arrhythmia drugs.

A CRT-D gives many patients more "peace of mind." They feel safer because the CRT-D will automatically treat their arrhythmia. A CRT-D may also help alleviate your heart failure symptoms, such as fatigue or shortness of breath. You may experience other benefits from a CRT-D. Your doctor is the best person to help you understand them.

What are the risks of having a CRT-D?

Your doctor is the best source of information about the risks of getting a CRT-D. Be sure to talk about all your questions and concerns. Some possible

risks of CRT-D treatment are discussed below.

A small percentage of CRT-D patients will develop a complication because of the implant surgery. They may include infection, a reaction to a drug used during surgery, blood loss, or damage to a blood vessel, the heart wall, or other organ. After the surgery, you will feel some discomfort, and you will be tired. As you recover, you will feel better. However, some patients continue to feel some discomfort where the CRT-D is implanted.

It is important to follow certain precautions after you get a CRT-D. Your doctor will discuss them with you. Also, read this booklet completely, and pay close attention to sentences that are labeled with the word "warning" or "important." Those sentences contain important safety information. For more information about precautions and warnings, see page 24.

When an arrhythmia occurs, CRT-D treatment may not end it, or treatment may make the arrhythmia worse. In either case, the CRT-D then delivers

stronger treatment to try to end the arrhythmia. The CRT-D may not always eliminate all symptoms of the arrhythmia. You still may feel lightheaded or dizzy, or you may faint.

Implanting the CRT-D System

What will the operation be like?

You will be under anesthesia during the operation. Once you are asleep, the doctor makes two incisions. The first incision is to implant the leads. One end of a lead goes in or on your heart. The other end will be plugged into the CRT-D.

The second incision makes a "pocket" or pouch just under your skin. Next, the doctor connects the leads to the CRT-D. They put the CRT-D in the pocket to hold it firmly in place.

Once the leads are connected, the system is checked to make sure it works properly. After the testing, your incisions are closed and you are taken to the recovery room.

Figure 7 shows some of the incisions commonly used for implanting leads and CRT-Ds.

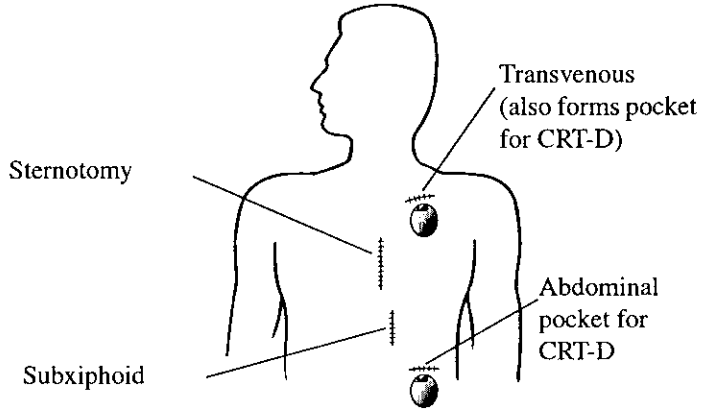


Figure 7. Incisions commonly used for implanting the CRT-D system.

What are the most common types of surgery used to implant the leads?

Transvenous: Transvenous means "through the vein." This type of operation is used for leads that are placed inside your heart. The doctor makes a small incision near your collarbone and threads the leads through a vein into your heart.

Thoracotomy: This is a general term used to describe several types of chest operations. A thoracotomy is used to place "patch" leads on the outside of your heart. These leads are thin oval patches made of rubber and wire mesh.

The operations described below are similar operations. The difference between them is where the incision is made.

Sternotomy: During this operation the incision is made over your breastbone, or sternum. This is the type of operation that is commonly used in coronary bypass and heart-valve surgery.

Subxiphoid: During this operation the incision is made slightly to the left of your breastbone.

The choice of operation depends on your heart condition, any previous chest surgery you may have had, your anatomy, and other factors.

What is recovery like?

When you wake up from the anesthesia, you will probably be drowsy and feel some discomfort. You will be connected to an electrocardiogram (ECG) to watch your heart and its activity. In fact, your heart will be watched closely during the entire time you are in the hospital.

By the following day, you will probably be up and walking about. Every patient's recovery from the operation is

different, so ask your doctor how long you can expect to be in the hospital.

Before you leave the hospital, your doctor may test the CRT-D again. To make sure your CRT-D works properly, the doctor will make the CRT-D deliver therapy, usually a shock. During this testing you may be mildly sedated; however, you should be able to feel the shock.

After your CRT-D is implanted, you should return to your normal activity as soon as you feel up to it. You may feel a little tired or sore at first, so build slowly up to your normal routine. Before long you'll feel more like yourself.

You will need regular checkups after you are released from the hospital. Your doctor will let you know how often these checkups should be. Once you're at home you should pick up your life where you left off before your operation. You will feel stronger with each day and can resume your normal activities.

Home From the Hospital

Listed below are a few important things to remember.

1. **You should follow your doctor's instructions for returning to your normal activities and for rehabilitating your heart.**
2. **Feel free to talk with your doctor if you or your family find it hard to adjust to the CRT-D once you get home.**
3. **If you need medications, take them as directed.**
4. **Follow the doctor's instructions about receiving a shock** **(see page 11).** If the doctors instructions are to phone them after receiving a shock, place the phone number in a convenient place.
5. **See your doctor for regular check-ups.** The doctor will discuss a specific schedule for you to follow. If you are planning to travel or if you are moving, ask your doctor for the name of a doctor in the new location who can treat you and your CRT-D.

6. **Avoid any rough contact with your CRT-D.** Avoid contact sports such as wrestling and football. Report any signs of soreness, swelling, or redness near your incisions to your doctor.
7. **Always carry your ID card.** You will receive an identification card after your CRT-D implant. It will contain information about your CRT-D. Place the card in your wallet or carry it with you at all times. Show your card if you are ever in an emergency, are admitted to a hospital, see a new doctor or need to prove that you have a CRT-D.
8. **Have your family members learn CPR.** This is a wonderful lifesaving skill for an emergency.
9. **Call your doctor immediately if** the CRT-D pocket becomes painful, swollen or red (whether or not you also have a fever) or if you experience palpitations, dizziness, or fainting.

Cautions and Warnings

Most electrical and mechanical devices have no effect on your CRT-D. Its built-in features protect it from the kinds of interference you are likely to encounter in your normal daily activities.

General Information

Any electrical equipment, appliance, or machine that you use should be in good working order. If the power plug is the three-prong type, make sure that the grounding plug is intact. Do not use three-wire to two-wire "cheater" plugs. An evaluation of wiring by an electrician, particularly in older homes, would identify any improper grounding.

Caution: Do not carry magnets or products containing magnets close to your CRT-D.

Avoid holding motor-driven appliances and machine-shop tools closer than necessary to your implant site.

When working with tools or appliances, be careful in situations where you could be injured if you become dizzy or receive a therapeutic shock from your CRT-D.

EMI

There are some things that produce very strong magnetic fields or electromagnetic interference (EMI) and may affect your CRT-D's function. Certain types of electrical or magnetic energy can interfere with your pulse generator's operation. You should do your best to avoid sources of EMI.

Use the following information as a guideline and discuss it with your doctor. If you have concerns about a specific type of equipment or appliance not listed within this booklet, check with your doctor. If you still have questions, contact St. Jude Medical at (408) 738-4883 (800-733-3455 in the USA).

Home Appliances

Assuming they are in good condition and the plugs have not been damaged or altered, the following items are safe to operate:

- kitchen appliances, including microwave ovens, can openers, blenders, toasters, electric knives
- televisions, VCRs, personal computers, AM/FM radios, remote controls, garage door openers

- major appliances, including washers and dryers, electric stoves, refrigerators, etc.
- electric blankets, heating pads

Avoid holding the following items closer than necessary to your implant site:

- hand-held appliances with motors, such as hair dryers and shavers
- light shop equipment, such as drills, table saws, etc.
- transmitters for radio-controlled equipment or toys

It's generally safe to work around spark-ignited internal combustion engines, such as lawn mowers, leaf blowers, automobiles, etc., but limit your exposure to ignition-system parts when they are in operation. If you're fixing your car, remember that your car's electrical system (alternators, high-tension ignition wires, spark plugs, and coil wires) can be a source of EMI.

Office Equipment

Most office equipment is safe to operate as long as it is in good working order and the plugs have not been damaged or altered. This includes computers,

electric typewriters, fax machines, pagers and copiers.

Security Systems

Metal detectors and anti-theft systems used in airports, stores and other locations create electromagnetic fields than can interfere with your CRT-D.

Anti-theft systems or Electronic Article Surveillance (EAS) systems such as those used at the entrances/exits or checkout counters of stores, libraries, banks, etc. emit signals that may interact with CRT-Ds. It is very unlikely that these systems will interact with your device. To minimize the possibility of interaction, just walk through the entrances/exits of these establishments at a normal pace and do not linger in these areas.

Metal Detectors: Walking through the metal detector archway will not harm your CRT-D. Be sure to pass through the archway at a normal pace and avoid lingering in the immediate area. Your CRT-D system has metal inside that may set off the airport security system alarm. If the alarm does sound, be sure to present security personnel with your CRT-D identification card. If a search

with a hand held wand is performed you should stress to security personnel that the search should be performed quickly and that they should avoid holding the wand over your CRT-D for a prolonged period.

Industrial Equipment

Large industrial equipment, such as generators and electric motors, often generate strong electromagnetic fields that can interfere with your CRT-D. Avoid standing near large motors or other electromechanical equipment. Make sure that the equipment is properly grounded before working near it.

Medical Equipment

Although most medical equipment will have no effect on your CRT-D, some may affect its function. Always tell the doctor or nurse that you have a CRT-D.

You can safely undergo diagnostic X-rays including fluoroscopy, dental and chest X-rays, computed tomography (CT) scans, and mammographies. Ultrasonic dental cleaners should not affect your CRT-D.

Caution: Do not undergo any diathermy procedure, even if your

with a hand held wand is performed you should stress to security personnel that the search should be performed quickly and that they should avoid holding the wand over your CRT-D for a prolonged period.

Industrial Equipment

Large industrial equipment, such as generators and electric motors, often generate strong electromagnetic fields that can interfere with your CRT-D. Avoid standing near large motors or other electromechanical equipment. Make sure that the equipment is properly grounded before working near it.

Medical Equipment

Although most medical equipment will have no effect on your CRT-D, some may affect its function. Always tell the doctor or nurse that you have a CRT-D.

You can safely undergo diagnostic X-rays including fluoroscopy, dental and chest X-rays, computed tomography (CT) scans, and mammographies. Ultrasonic dental cleaners should not affect your CRT-D.

Caution: Do not undergo any diathermy procedure, even if your

CRT-D has been turned off. It could cause damage to the tissue around the implanted leads, or permanent damage to the CRT-D.

Caution: Try to avoid electrical nerve and muscle stimulators (TENS units). They may interfere with the function of your CRT-D.

Caution: Magnetic resonance imaging (MRI) scans can severely damage your CRT-D. When you are in or near an MRI room, your CRT-D might be affected.

Recreation

Amusement park rides should not affect your CRT-D, but be cautious of rides that have large sparks, such as bumper cars. It's also best to avoid activities that involve severe shaking, like horseback riding or bumper cars. Depending on the programming of your device, this type of activity may inappropriately cause a temporary increase in the rate of pacing.

Most tanning beds will not affect your CRT-D.

Caution: Don't touch the antenna of an operating CB or ham radio. It may

cause interference with the function of your CRT-D.

Arc Welding

Caution: Arc welding can affect your CRT-D because of the strong electromagnetic fields produced. Here are some recommendations to help minimize interference:

- Wear non-conductive gloves, such as leather (must be dry), fireproof cloth, or rubber. Keep your shoes dry, and don't weld in a wet or damp area.
- Use acetylene or other non-electric welding when the application is suitable.
- Don't use higher current settings than necessary.
- Keep the cables close together by twisting them around each other. Place the welding machine and excess cable away from you.
- Don't weld using repeated short bursts; wait about ten seconds between each weld. If you have difficulty starting a weld on a dirty surface, don't strike the rod rapidly, and wait about 10 seconds between each start.
- If you feel dizzy, light-headed or faint, stop welding immediately. Lay

down the rod and move away from the welding machine. Arrange your work so that if you drop the handle and the rod because of a dizzy spell, they will not drop into the metal being welded. For similar reasons, don't work on a ladder or in a cramped, confined location.

- Don't work alone. Have someone else around when you're welding.

Cellular phone

Recent studies have suggested that if a cellular phone is held close to a CRT-D (within 6 inches), the phone may affect the operation of the defibrillator. This may be either because of radio signals produced by the phone or because the phone contains a magnet. It is possible that a cellular phone might stop your CRT-D from delivering therapy or cause it to deliver therapy that is not needed. The effects produced by a cellular phone are temporary. If you move the phone away from the CRT-D, the CRT-D works normally again.

Caution: Because there are so many different cellular phones and because people and their CRT-Ds will each react differently, St. Jude Medical cannot

make recommendations that cover all patients and all cellular phones.

Here are some general guidelines for cellular phone use:

- Keep a hand-held personal cellular phone at least 6 inches (15 cm) from your defibrillator. Portable and mobile cellular phones generally use more power than hand-held models. For phones transmitting above three watts, keep the phone at least 12 inches (30 cm) from your CRT-D. Hold the phone to the ear opposite the side of the implanted device.
- Some phones send out signals when they are turned ON but are not being used (for example, in the listen or standby mode). Therefore, do not carry the phone in a breast pocket or on a belt within 6 inches of your CRT-D. Store it on the side of your body opposite the CRT-D.

Caution: Do not hold a cellular phone too close to your CRT-D. It may affect CRT-D function.

Contact St. Jude Medical for more information about using a cellular phone.

Learning to Live with Heart Disease

My illness has changed my life. How do I cope with it?

Serious heart disease is a blow that can affect your emotions as well as your body. At times you may feel anxious, afraid, depressed, even angry. There are many ways to cope:

- Talk to other people. It will help you work through your feelings. Talk to your doctor, a nurse, a counselor, a friend or family member, or a member of the clergy.
- Talk to your doctor about joining a support group. Sharing experiences with other CRT-D patients lets you know that you are not alone.
- Exercise regularly. It's a great way to reduce stress, build strength and gain confidence. Remember to ask your doctor before starting an exercise program. There is more about exercise later in this guide.
- Learn more about relaxation. Too much stress can wear you down and increase your chance of getting other

illnesses. It also disturbs your sleep and makes you cranky.
One good way to relax is to sit quietly with your eyes closed for 20 to 30 minutes twice a day. A short nap each day or a slow walk every morning can also be calming.

- Take care of yourself. Avoid alcohol and caffeine. And quit smoking. These habits can make anxiety and depression worse.

My spouse/family member is the patient. How can I help?

If a family member or friend is the patient, it is natural for you to have the same fears and worries. There are several things that can help both of you cope with their condition. For example, listen when they want to talk. Your loved one needs reassurance that they have your support. However, you should not deny that their illness is serious.

Drugs

Why do I need medication if I have a CRT-D?

Anti-arrhythmia drugs and the CRT-D can work together to make your abnormally fast heart rate easier to stop or occur less frequently.

In addition to your CRT-D, you will also need to take medication as part of your heart failure treatment plan.

Warning: Do not stop taking your drug(s) without the advice of your doctor!

I'm told that my drugs may need periodic adjustments. How will that be done?

Your doctor may find it necessary to increase or decrease your drug dosage. They may also add a new drug. Your heart must be watched closely while your doctor makes these changes. This means that you may need to stay in the hospital. The length of the hospital stay varies from patient to patient.

Is it OK to take my anti-arrhythmia and heart failure drugs with other drugs?

Make sure your doctor knows about all of the drugs you are currently taking. Tell your doctor whenever another doctor prescribes a new drug.

Food and Nutrition

I already have heart disease. Will changing my diet benefit me?

It is never too late to improve your diet. The American Heart Association recommends a diet high in fiber and low in fat, cholesterol and sodium (salt). High-fat, high-cholesterol foods (such as whole milk dairy products, red meats and junk foods) contribute to hardening of the arteries—a major cause of heart attacks and strokes. High-fiber foods are rich in vitamins and minerals and make you feel full and satisfied for fewer calories.

What are good sources of fiber?	Oatmeal, fresh vegetables, and fruit are good sources of fiber. Fiber helps lower blood cholesterol and prevents constipation.
How much fat can I have?	Generally, you should keep saturated fat to less than one third of your daily fat intake—10% of daily calories. A fat-rich diet raises blood cholesterol and can lead to weight gain, both of which contribute to heart disease. Most packaged foods list fat, cholesterol and fiber content on their labels. Talk with your doctor about your specific dietary requirements and changes you may need to make in your eating habits. A registered dietitian is a wonderful resource to help you learn more about eating to be "heart healthy."
What is the best way to control my fat intake?	Let balance, variety and moderation guide you. There is no need to give up meats and dairy products. Eat lean cuts of meat and low-fat dairy items. Save high-fat foods such as potato chips and cheesecake for special occasions. Avoid saturated fats. These are found mostly in red meats, whole milk products, and foods made with palm

and coconut oil. In general, saturated fats come from animals.

Sometimes it is not obvious that a food is high in fat. For example, one ounce of trail mix with peanuts and raisins has as much fat as one chocolate chip cookie.

What foods are high in sodium?

Salty foods and those foods with preservatives generally have a high sodium content. For example, broth, soy sauce, cold cuts, hot dogs, chips, nuts and pretzels are high in sodium. Sodium may encourage high blood pressure and water retention. Reducing the sodium in your diet is simple if you take note of the food products labeled as "low sodium." Ask your doctor how much sodium is OK for you.

Besides diet, what affects heart health?

Many factors contribute to heart disease. Some things you can't change, like your sex, race, age, high blood pressure and family. You can change other things that affect your heart, like smoking, a poor diet and lack of exercise. If you have high blood pressure, have it checked regularly and follow your doctor's instructions to keep it under control.

Why is being overweight dangerous for a person with heart disease?

When you're overweight, the extra pounds make your heart work harder. They can also lead to high blood pressure and diabetes, which are bad for the heart. Losing excess weight eases the strain on your heart.

If you diet, you should lose weight slowly, ideally one-half to one pound a week. You will be more likely to keep the weight off. Your doctor can help you set up a weight-loss program.

Exercise

What kind of exercise can I do after surgery?

After surgery you should resume your normal activity as soon as you feel up to it. You may feel a little tired or sore at first, so build slowly up to your normal routine. Before long, you'll feel more like yourself. Your doctor may give you special exercise instructions or suggest that you start a cardiac rehabilitation program.

There are only a few exercise restrictions to keep in mind. For example, avoid contact sports like wrestling or football, since they may damage the CRT-D or the leads. Consult your doctor before doing strenuous or repetitive upper-body exercise like weight lifting or softball.

Warning: Avoid contact sports after you get your CRT-D. Also, get your doctor's approval before starting an exercise program, especially if it involves upper-body activity.

What is cardiac rehabilitation?

It is an exercise and education program to help you regain your strength and improve your heart. A typical program consists of regular exercise monitored by medical professionals. Walking and bicycling are the most common exercises. You will also attend classes to learn more about your heart, the reasons for your heart disease, and how to live a healthier life.

Ask your doctor if this kind of program would be good for you. They will develop one specifically for you.

Do I need to go to a special facility for cardiac rehabilitation?

Not always. You may begin your cardiac rehabilitation program in a monitored setting but continue at home. An example of exercise you might do at home is a twenty-minute walk three times a week. Monitor yourself. If you begin to feel weak or short of breath, slow down or stop until you feel stronger or catch your breath. Over time, you will build up your strength and endurance.

No matter where you exercise, be sure to wear loose clothing and comfortable walking shoes. Feeling comfortable will help you get the most benefit and enjoyment from exercising.

What if my CRT-D delivers therapy when I exercise?

This does not happen very often. But remember, the CRT-D is watching how fast your heart is beating and during exercise your heart rate will increase. Generally your doctor makes allowances for this increase when they program your CRT-D. In the isolated case, your CRT-D may need to be adjusted or "fine tuned" to avoid unnecessary therapy.

If you do receive a shock while exercising, stop. If you are in the hospital or office, tell the person attending you. If you are at home, notify your doctor.

What about sex?

How will having a CRT-D affect my sex life?

Your sex life should not be affected by having a CRT-D. Once your incisions heal and your doctor gives the okay, you and your partner can resume relations when you want to. Healing is usually complete within 12 weeks but it varies from one patient to another.

Is there any chance the CRT-D will deliver therapy during sex?

Physical activity (of any kind) is not likely to cause the CRT-D to deliver therapy. But if it does happen during intercourse, stop and notify your doctor just as you would if it happened during exercise.

Will I have problems with my sexual performance?

CRT-Ds rarely affect sexual performance. Impotence may occur for a short time. It may be due to worry about receiving therapy or medications you are taking. If the problem doesn't get better, discuss it with your doctor.

You may fear that your partner will be hurt if the CRT-D delivers a shock. They may feel a tingle, but nothing more.

In short, you can pick up where you left off. The key lies in becoming comfortable with the CRT-D.

Is it possible to dislodge the CRT-D? Will pressure affect its operation?

The CRT-D is firmly fixed in the pocket under your skin and the leads are well secured to the CRT-D. Pressing on the CRT-D does not affect how it functions. However, avoid rubbing your CRT-D or the area surrounding it. Avoid rough contact that could impact your implant site.

Glossary of Terms

Arrhythmia An abnormal rhythm of the heart.

Atrium One of the two upper chambers of the heart. These chambers receive blood from the body and pump it to the ventricles, the lower chambers of the heart.

Bradycardia An abnormally slow heart rate, less than 60 beats per minute. However, if a person is in very good physical condition, it is natural for their heart rate to be below 60 beats per minute.

Cardioversion The use of electric shock to stop rapid heartbeats, usually ventricular tachycardia.

Contraction A squeezing of the heart muscle that forces blood out of the heart. This contraction is the heartbeat.

CRT-D	A cardiac resynchronization therapy defibrillator. It is an implantable cardioverter defibrillator that includes a pacing feature to help resynchronize (coordinate) the lower heart chambers. Also known as an ICD-CRT, ICD with biventricular pacing, or heart failure ICD.
Defibrillation	The use of electric shock to stop rapid heartbeats, usually ventricular fibrillation. Defibrillators use paddles on the outside of the chest or internal electrodes placed directly on the heart.
Electro-cardiogram	Often called an EKG or ECG, it is a "picture" showing the electrical activity of the heart.
Electrode	The portion of the lead that transmits and records electrical signals to and from the heart.
Electro-magnetic Interference	Also known as EMI, this is magnetic or electrical interference from machines or devices which can interrupt the normal operation of a pulse generator.
Electro-physiologist	A doctor who specializes in diseases of the electrical system of the heart.

Electro-physiology (EP) Test	A test in which your electrophysiologist evaluates the electrical system of your heart. During this evaluation, the electrophysiologist may also cause your arrhythmia to occur. This is how CRT-Ds and antiarrhythmic drugs are tested.
EMI	See "Electromagnetic Interference."
Heart Failure	Heart failure (HF) is a complex clinical syndrome that results when the heart muscle is weakened and can no longer pump blood as efficiently as a healthy heart.
Incision	A cut produced by a surgical instrument in order to perform surgery.
Lead	A special wire connected to the pulse generator and placed in or on the heart.
Pulse Generator	The part of the CRT-D system made up of the electronic circuitry and the batteries, which are packed and sealed in a metal container.
Sinoatrial (SA) Node	The small mass of special muscle tissue that generates a heart beat. It is located in the upper right chamber of the heart.

Thoracotomy	An incision made in the chest when performing heart or lung surgery.
Transvenous	To place something through a vein or the venous system.
Ventricles	The two lower chambers of the heart. These chambers pump the blood out of the heart into the body.
Ventricular Fibrillation	A quivering of the ventricles during which essentially no blood is pumped to the body. It can lead to death if an electrical shock is not quickly delivered to the heart to restore a normal heart beat.
Ventricular Tachycardia	A rapid beating of the ventricles. This rapid beating reduces the heart's pumping efficiency and can therefore lead to fainting, dizziness, weakness, blind spots, and unconsciousness. If this rhythm is not treated with medications or an electrical shock, it can lead to the more serious problem of ventricular fibrillation.

Index

R

S

T

V

W

X

Notes

ST. JUDE MEDICAL

CARDIAC RHYTHM MANAGEMENT

15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822
+1 888 sjm-crmd

701 E. Evelyn Ave.
Sunnyvale, CA 94086 USA
+1 408 738 4883

SE-175 84 JÄRFÄLLA
Sweden
+46 8 474 40 00

www.sjm.com

June 2004
40001530/002
Part No. 40001530-001